UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

The Honorable Freda L. Wolfson, U.S.D.J.

BRACCO DIAGNOSTICS, INC.,	Civil Action No. 03-6025
Plaintiff,	**OPINION**
vs.	
AMERSHAM HEALTH, INC., et al.,	
Defendants.	

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Glossary of Abbreviations

AHI	Amersham Health Inc. (U.S.-based Counterclaim Plaintiff)
ASD	GEH Area Sales Director
AWC	Adequate and well-controlled study
BDI	Bracco Diagnostics Inc.
[witness] D	Designated deposition testimony
[witness] Dec	Designated declaration
CE	Continuing Education for doctors, nurses and technicians
CIN	Contrast Induced Nephropathy or renal damage caused by x-ray contrast medium
CM	Contrast Medium or Contrast Media
CME	Continuing Medical Education for doctors
CMS	Centers for Medicare and Medicaid Services
CT	Computer Tomography. A type of x-ray procedure where the CM is given by i.v. administration
CT DCAM	Novation's DCAM for CT (i.e., x-ray) contrast media
CT+MR DCAM	Novation's DCAM for both CT (i.e., x-ray) and MR contrast media
C x	Bracco's Proposed Post-Trial Conclusion Of Law at paragraph "x"
Dx : y	Defendant's Trial Exhibit "x" at page "y" (where y is the last three numbers of a Bates number, if applicable)
DCAM	Decision Criteria Award Matrix
DHRxns	Delayed Hypersensitivity Reactions

Dual DCAM	Novation's DCAM for a dual source award for both CT (i.e., x-ray) and MR contrast media
FC	Financial Criteria
FDA	United States Food and Drug Administration
GEH	GEH Healthcare, which acquired the three named defendants, who in turn acquired Amersham and Nycomed
GPO	Group Purchasing Organization
HOCM	High Osmolar Contrast Medium
i.a.	intra-arterial (form of administration directly into an artery)
i.v.	Intra-venous (form of administration directly into a vein)
IOCM	GEH's trademarked term, Isosmolar Contrast Medium
ITB	Novation's June 14, 2004 "Invitation To Bid"
JACC	Journal of the American College of Cardiology
KOL	Key Opinion Leader
LBB	"Low Best Bid" or "Low Best Bidder"
LOCM	Low Osmolar Contrast Medium
MA	Meta-Analysis, a type of clinical study analysis
MACE	Major Adverse Cardiac Events or Major Adverse Clinical Events, depending on the study design
MR DCAM	Novation's DCAM for MR contrast media
MRI	magnetic resonance imaging contrast media
NAC	N-acetylcysteine

NEJM	New England Journal of Medicine
NFC	Non-Financial Criteria
NQWMI	Non-Q-wave Miocardial Infarction
RFA	GEH's responses to Bracco's requests for admissions
RFP	GPO Request For Proposal
OTSheet	Omnipaque Toss Sheet
Px : y	Plaintiff's Trial Exhibit "x" at page "y" (where y is the last three numbers of a Bates number, if applicable)
PCI	percutaneous cardiac intervention
PO	Pretrial Order
POA	Plan of Attack or Plan of Action
PTCA	Percutaneous Transluminal Coronary Angioplasty
SR	Systematic Review (type of clinical study analysis)
TCT	Transcatheter Cardiovascular Therapeutics (TCT) Scientific Symposium
TF	Novation's ICM Task Force
URTBrochure	Unchallenged Renal Tolerability Brochure
x T y	Trial Transcript Volume "x" at page "y"
VVAT	Visipaque Value Analyis Tool
<u>Contrast Agents</u>	
Isovue	Bracco x-ray contrast agent
ProHance	Bracco MRI contrast agent

MultiHance	Bracco MRI contrast agent
Visipaque	GEH x-ray contrast agent
Omnipaque	GEH x-ray contrast agent
Omniscan	GEH MRI contrast agent
Optiray	Tyco/Mallinckrodt x-ray contrast agent
Hexabrix	Tyco/Mallinckrodt x-ray contrast agent

WOLFSON, United States District Judge:

This matter comes before the Court upon a Complaint brought by Plaintiff Bracco Diagnostics Inc. (referred to herein as "Bracco") against Defendants Amersham Health Inc., Amersham Health AS, and Amersham PLC (collectively referred to herein as "GEH") for alleged false advertising in violation of the Lanham Act. In response, GEH filed a Counterclaim against Bracco for alleged false advertising of its own line of products. Bracco and GEH have competing product lines in the contrast medium healthcare industry. The crux of Bracco's case is that GEH has falsely advertised the superiority of its product, Visipaque, over Bracco's product, Isovue. The Court conducted a thirty-nine day bench trial with numerous experts[1] and witnesses testifying as to each party's product lines and the underlying clinical studies upon which GEH and Bracco have based their advertising campaigns.

In light of the evidence presented at trial, the Court concludes that GEH did promote false messages which were sufficient in number to constitute actionable commercial advertisements or promotions under the Lanham Act, however the Court finds that Bracco has failed to establish a causal nexus between GEH's false advertisements and Bracco's alleged lost profit damages. In that regard, the Court determines that the greater number of GEH's advertisements were in fact true and based on reliable scientific studies. The messages that the Court finds false are those that extrapolate beyond the studies' results. In connection with Bracco's claim, the Court finds that an injunction and damages for post and future corrective advertising are appropriate remedies to prevent future

[1]Since this was a bench, not a jury, trial, the parties agreed to forego pre-trial Rule 104 hearings and instead permit the experts to appear once at trial and that the Court could rule on the Daubert motions in its findings of fact and conclusions of law - after hearing the testimony. See infra Section III.

violations of the Lanham Act. As to GEH's counterclaim, GEH dismissed its claim for damages and Bracco has stipulated that it no longer uses the offending advertisements. Thus, although the Court finds that certain of Bracco's ads were false, nonetheless, an injunction is not appropriate in this case. In addition, the Court imposes an alternative dispute mechanism applicable to both parties for safeguarding against any future false advertisements.

I. Overview

A. Parties and Product Lines

GEH and Bracco market and sell x-ray contrast media ("CM") in the United States. CM are classified by osmolality. HOCM (high osmolar CM) have osmolalities of greater than 1500 mOsm/kg. LOCM (low osmolar CM) have osmolalities between 600 and 850 and include Omnipaque (iohexol), Isovue (iopamidol), Hexabrix (ioxaglate), Ultravist (iopromide), Iomeron (iomeprol), and Optiray (ioversol). The osmolality of blood is approximately 290 mOsm/kg. Both GEH and Bracco market LOCM; GEH sells Omnipaque and Bracco sells Isovue. In addition, GEH also markets a product called Visipaque (iodixanol) which it classifies as iso-osmolar or isotonic, (i.e. - its osmolality equals blood). Visipaque is referred to in various medical literature as an IOCM (iso-osmolar CM). Part of GEH's advertising campaign is that its iso-osmolar CM performs better than LOCM. Visipaque was introduced in 1996, ten years after Omnipaque and Isovue were marketed and is the only "IOCM" available in the U.S.

B. Procedural History

On December 16, 2003, Bracco filed a four count Complaint in the District of New Jersey against GEH alleging: (1) dissemination of false and misleading advertisements in violation of Section 43(a) of the Lanham Act; and (2) N.J.S.A. 56:4-1, et seq.; (3) violations of the common law

of unfair competition; and (4) negligent misrepresentations. GEH filed an Answer and two counterclaims against Bracco alleging: (1) dissemination into commerce of allegedly false and misleading statements concerning the relative safety of Omnipaque, Visipaque, and Isovue in violation of Section 43(a) of the Lanham Act; and (2) N.J.S.A. 56:4-1, et seq. GEH's counterclaim was filed against Bracco and its foreign affiliates, Bracco S.p.A. and Bracco Imaging S.p.A. However, pursuant to an Order entered on September 7, 2004, GEH's counterclaim against Bracco's foreign affiliates was dismissed for lack of personal jurisdiction. Motions for Summary Judgment were denied by the Court, after which, a thirty-nine day bench trial was conducted between the period of May 7, 2007 and December 2007, followed by further written submissions. The Court held a hearing on May 15, 2008, wherein the Court resolved evidentiary objections regarding the admission of disputed exhibits. Subsequently, the parties submitted proposed Findings of Fact and Conclusions of Law, which were supplemented by Reply briefs and additional Daubert briefs to exclude expert testimony proffered by both sides.

II. Findings of Fact

A. Bracco's Case in Chief

As set forth below, the Court finds that GEH advertises and promotes Visipaque with establishment claims asserting that studies show it is superior in several ways, including renal and cardiovascular safety, pain, heat and discomfort. The Court further finds that: the spike in Visipaque sales that started in 2003 was primarily due to the publication of the NEPHRIC study; GEH's advertising of NEPHRIC through true renal ads and promotions also contributed significantly to GEH's success with Visipaque; only a fraction of GEH's ads were false; while these false ads were sufficient in number to constitute actionable promotions under the Lanham Act, they were not the

cause of GPO contracts being awarded to GEH. In addition, the Court finds that the limited false ads disseminated by GEH were not willfully false because GEH relied on scientific studies, which have not been disproved, and that GEH had a protocol in place for approving advertisements that attempted to ensure against falsity.

1. GEH's Establishment Claims Of Renal Superiority

In late 2002 to early 2003, GEH focused its ads and promotions on renal establishment claims based on the NEPHRIC study; GEH claimed that Visipaque had superior renal safety over competitor drugs or LOCM. (See, e.g., P1672 ("[w]e will begin to shift our focus from a Excellent Patient Comfort/Cardiac Safety message to the prime message being Excellent Renal Tolerance"), P106, P849:932, P1269:219, P1147:261, P1265:203, P1266:208; 13 T 72, 16 T 95, 6 T 58-79,102-104, 17 T 69-70). These claims are of two types: the data (from NEPHRIC or other studies) show (a) Visipaque is superior to a LOCM or all LOCM or (b) Visipaque is as good as or better than LOCM with pretreatments.[2] GEH uses the term LOCM to obscure the fact that its own drug, Omnipaque, was the comparator in the NEPHRIC study, and to thereby lessen any impact on Omnipaque, specifically, and to generalize the results to all LOCM, including Isovue. (P1534, P1535, P1519, P1523; 13 T 62-63).

GEH designed and then planned to disseminate the claims through multiple promotional channels (print media, websites, GEH representatives, medical doctors and CME's). (8 T 4-15,81-

[2] See, e.g., GEH's Vice President of Sales, Mr. Donald J. Quinn, testified that statements like "Visipaque is safer renally than other LOCM" would only be made in the context of a clinical paper, making them establishment claims. (7 T 206-211).

129, 135-37, 17 T 53,64-68; P869 ('03), P849 ('04), P2098 ('05)).[3] GEH determined that the claims were the most effective way to convert sales based on its experience, (e.g., 7 T 178), and marketing research (P196, P696, P1400, P1700, P1716:739, P1742, P2038; 13 T 27-28).

The GEH representatives were instructed in Plans of Action ("POA") (e.g., P2101:559 (e.g., "less incidence of CIN")), memoranda (e.g., P102 ("top 3 messages"), P104, P353, P398:394, P639:552 ("(CIN) in high-risk patients was 11X less likely … than with LOCM"), P640, P661, P662, P696, P772, P1832:194, P2027, P4249; D790), training (e.g., P651 (e.g., "Visipaque is clinically proven to be … safer for high risk patients"), P1136:370 ("safer")) and Medical Bulletins (e.g., P402:563 (e.g., "NEPHRIC data clearly demonstrate … a significantly better renal safety profile than a traditional [LOCM], such as iohexol, in at-risk patients"), P538:888, P798:078) to disseminate the claims. (E.g., P85, P632, P774, P1008, P1012, P1021, P1080, P1082, P1136, P1178, P1373:182, P1561, P1572:893, P1681, P1699, P1721, P2099, P2100, P2101, P3708; 8 T 68-81,129-135,148-80, 9 T 5-53,65-80,88-102).[4]

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[3] See also the testimony of Peters, Quinn, Gehris, Kerachsky, Vitti, Murray and Russell describing the claims and the plans. Other descriptions of the claims and plans starting in 2003 (P17, P19, P866, P1579, P340, P341, P854, P855, P856, P857, P1163) and other reports (P417, P792, P1004, P1010, P1155, P1169, P1362, P1365, 1436:635, P616, P1449, P1450, P1584) are all consistent. Plans prior to 2003 describe the same type of establishment and superiority claim strategy since the product launch in 1996: P2111-13,P2097, P1441, P875, P877, P1648.

[4] For example, P2027:853-7 and P2026:853-7 identify some of the tools and the claims (e.g., "Visipaque has highest safety profile") to be made from them. Additional instructions to deliver the claims are: P398, P399 (first page), P419, P424, P603, P634, P635, P645, P678, P688, P690-2, P694A, P711, P714, P770, P789, P798, P1164, P1249, P1250, P1373, P1388, P1424, P1692, P1714, P1715, P1934, P2025, P2034, P4247, P4249, P4263-5; 16 T 34-39, 41-42, 48-51, 56, 132-134, 136-139; POA's for GPO's: P451, 452, 623, 625, 626, 630, 680, 684, 709, 732, 788, 1363, 1718.

The claims were then disseminated nationwide using print media, GEH representatives and continuing medical education ("CME") presentations. The print media (e.g., brochures, websites, presentations, articles) with extracted messages that were identified in Bracco's pretrial brief and discovery responses and addressed at trial include:[5]

- Press releases on its website: "[]The NEPHRIC data clearly demonstrate that Visipaque™ offers a significantly better renal safety profile than traditional low osmolar non-ionic contrast media in at-risk patients . . . . We believe that the data strongly support Visipaque™ as the agent of choice for these patient groups." P2449:379, P69:915, P254:863, P772:340, P1448:898, P4149:p2; 7 T 68-69.

- Computer Tomography (CT) brochures: "Nonionic Dimer Provides Lower Osmolality, Reduced … CIN" "CIN": "Nonionic Dimer": "↓" ; "Nonionic Monomer": "↑". P410:965, 3649:408, 3649A:408; D2324:117.

- Novation presentation: "Isosmolar VISIPAQUE. . . Demonstrated to significantly reduce incidence of Contrast-induced Nephropathy (CIN)." P2161:391. GEH rep efforts included the delivery of the claims and print media in face-to-face detailing of administrators, technicians, nurses and doctors, for which records were presented at trial from GEH's sales call record system, emails and memoranda, e.g."[6]

- Sales Calls Records: "Discussed patient types that would benefit from Visipaque usage over Isovue. Re-affirmed with Nephric study." P2312:A637284, P4049:A637284. "Discussed having hospital start using Visipaque for high-risk patients in CT. Detailed Nephric study and core visual aid to support benefits of isosmolar Visipaque vs. Isovue." P2312:A637355, P4049:A637355. "[C]linicaI studies, nephric etc show less risk nephrotox vs ... Isovue for [high risk] pts ...." P2312:A659673, P4049:A659673. "reviewed why Visi. is the best for kidneys." P2312:A670058, P4049:A670058. "Approached dr. with nephric focus and

[5] See also P1450:112, 4180:p14, 410:966, 141:486, 3089B:710, 2508:763A, 4163:763A, 2505:756A, 4155A:736, 4160:756A, 2506:758A, 4161:758A, 3448A:p1, 2956:734, 779:698-99, 1013:792-93, 782:897, 254:863, 3168A:408, 4089:510, 55:825, 1363:745, 2506:759A, 2511D:783A, 4161:759A, 4166D:783A, 333:745, 3089A:702, 4089:440, 142:507, 2304:p3, 2300:p3, 729:013, 50:772. Bracco also includes the New England Journal of Medicine ("NEPHRIC") article (P2467, P4176) and the Journal of the American College of Cardiology ("RECOVER") article by McCullough, et al. (P3807) as false promotions.

[6] Additional emails and memoranda: P693:396, 415:126, 707:679, 3709:402, 436A:435, 2730:066: 2520:907A, 2529:411.1; 16 T 99-114.

differentiating vis from locm class with regards to osmoality. Reminded dr. that patients are 11 times likely to have CIN with the locm class than visi." P3682:Omni/3727, 4049:Omni/3727.[7] [8]

- Consorta detailing: "Baluchi [from Consorta] asked about Isovue with respect to Omnipaque/LOCM as positioned in NEPHRIC. We made the point that Omnipaque represents a LOCM (gold standard) and confirmed his key take away that it is isosmolar versus low-osmolar that was studied, not necessarily Visipaque vs. Omnipaque." P682:286. "I…discussed the attributes of Isosmolar Visipaque including it's impact on CIN -- a clinical issue just coming to light; it's elimination of costly drug therapies (fenladopan) to prevent CIN with std LOCM". P793:514.

- HPG detailing: "Ami presented the Nephric data to Lew and he was very interested in the info. *He told her that one criticism of this paper was that it was not a head to head with Isovue. Ami showed him the list of references that prove the incidence of CIN with Isovue*

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[7] Additional sales call records are P3689L-1, P3689M-1, P3493F, P3434, P3437. P3689H, L, M and P3493, all exhibits that were attachments to Mr. Russell's expert reports and contain Mr. Russell's initial analysis of GEH's sales call records. P4049 is Mr. Russell's final sales call analysis of GEH's combined sales call records (P2312 & 3682), being entered into the record on a laptop computer – the only way the exhibit is viewable, and was provided to the Court and GEH on June 12, 2007. Before then, Mr. Russell removed ambiguous sales calls from the on-message calls in P4049, including seven of the eleven GEH cross-examined Mr. Russell on at trial. P3493F: Omni/35994, 79270 (duplicate Visi/153580 removed); P3493G: Omni/54842, 14153; P3493K: Omni/17593, 32829, 12243. Mr. Russell testified why the remaining four were on-message calls. (18 T 34-38). However, the Court finds that his testimony as to on-message calls is not reliable and therefore is excluded. See infra pp. 52, 82-83.

[8] Bracco submitted a laptop as exhibit P4049 with Concordance search software and a database representing Mr. Russell's final sales call analysis. GEH objected to the admission of the laptop into evidence, suggesting that it is prejudicial; however the Court has determined that such a searchable database is the only reasonable way that the Court can sift through the large number of sales call notes and therefore, admits it into evidence. Bracco asks the Court to use the following search strings for additional representative sales call notes: "((visi*). COMMENTSLONG. and ((less adj10 (risk or CIN)) or (better or improved)). COMMENTSLONG. and (renal or kidney or risk or nephric) .COMMENTSLONG.) or (((visi* or iocm) adj2 locm). COMMENTSLONG.). Bracco avers that these searches return hundreds of sales call records, the overwhelming majority of which show sales representatives delivery of similar messages. The Court reviewed the submitted laptop with its accompanying database of sales call notes and finds that even when running the suggested search strings that the sales call notes only provide a small percentage of what would be considered actionable messages.

is equal to that of Omnipaque so it is reasonable to draw a correlation that the results of Nephric would be the same if Isovue had been used." P663:942 (emphasis added).

The Court also finds that GEH-sponsored CME presentations for doctors (e.g., P849:946) delivered IOCM versus LOCM claims:[9]

- 2004 CME On CIN: "[R]ecent controlled trials have shown that *non-ionic Isosmolar contrast agents are superior to low-osmolar agents* in preventing CIN." P4251:210 (emphasis added). "The use of iodixanol in at-risk patients appears to minimize the risk of CIN even without additional pharmacological prophylaxis." P4251:212.

At trial, GEH's sales rep, Mr. Joseph Murray, confirmed delivering these claims through the print media (e.g., press releases and articles) and CME-type presentations to customers in order to convert sales to Visipaque. (E.g., 16 T 31-49, 56-58, 81-88, 97-114; 17 T 49-51,64-132).

2. The Falsity Of GEH's Renal Establishment/Superiority Claims

The Court finds that certain assertions made by GEH were supported by the studies' (NEPHRIC and Chalmers) conclusions (e.g. - Visipaque may be renally superior over a LOCM - - Omnipaque), while others were not (i.e. - Visipaque may perform better than LOCM with prophylactics and Visipaque is renally superior over all LOCM). Bracco asserts that GEH's representations are false and misleading because: (a) the NEPHRIC study omitted results and has flaws that contradict GEH's claims (Pl.'s FOF ¶¶ 11-15,17); (b) the studies (NEPHRIC and Chalmers) cannot reliably (Pl.'s FOF ¶¶ 11-13) support a conclusion of Visipaque superiority over all LOCM; and (c) the weight of the clinical evidence is that Visipaque is not superior to all LOCM as a group or to Isovue individually (Pl.'s FOF ¶¶ 11-15,17). For example, Bracco asserts that results

[9] See also P2671:521, P527, P3831:619, P621, P624, P629-630, P632, P634, P636-38, P640, P4251:203, P209, P211-12, P2307:p21, P2281:p7, 9, 53, P2282:p49, P3455:p12-13, 16-17, 22, 26, P3512:p12-13, 16-17, 22, 26, P3619:924, P2157:151, P3834:915, 932, P3647:355, P3890:241, 246.

of studies done with intra-arterial ("i.a.") use are not reliable enough to predict with reasonable certainty intravenous ("i.v.") results, (see P1733)[10] [11]; furthermore, Bracco points out that no studies compare Visipaque to a LOCM combined with pretreatments or even head-to-head with multiple LOCM.

The Court finds: (1) while there were flaws in NEPHRIC, those flaws do not vitiate its results; (2) the NEPHRIC and Chalmers studies are not unreliable in their conclusions; and (3) it has not been established by the weight of clinical evidence that Visipaque is superior to all LOCM as a group or to Isovue individually. Although there has never been one adequate and well-controlled ("AWC") clinical study (let alone two, done the same way with the same drug) showing that Visipaque is superior to any LOCM (even Omnipaque), with or without pretreatments,[12] [13] the

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[10] The most significant GEH efforts in issue are those concerning CT, GEH's focus, in delivering the allegedly false claims. (8 T 178-180; 13 T 87; 17 T 80-81, 85-89; 15 T 161-162, 166-167; 20 T 15; P410, P419, P527, P772, P854, P855, P869, P1008:279, P1169, P1401, P1733, P2098). CT uses i.v. administration of CM where there are less safety risks, but GEH used i.a. administration studies in its CT claims. (e.g., P1733:481, P410; 17 T 81, 85-89; 34 T 83-84, 2 T 61-62).

[11] Bracco contends that GEH ads overextended their conclusions to low risk and no risk patients. (See, e.g., P1832; P1716; P1008:279). However, the Court disagrees and finds that GEH's ads properly focused on "at risk" patients.

[12] By FDA standards, such a study must be a randomized, double blinded, prospective (e.g., follow a pre-designed protocol), head-to-head comparison that is adequate and well-controlled. (E.g., Care (P4076)).

[13] At trial, GEH relied on a proposed theory, that iso-osmolar agents produce no free radicals in the body, to try to support its claims. GEH's theory is proven false by the CIN caused by Visipaque, and when NAC and sodium bicarbonate, which act by reducing free radicals, were found to reduce CIN from Visipaque (P2650, P3949). Stated differently, if GEH's theory were correct, Visipaque would cause no CIN and NAC and sodium bicarbonate should have no effect with Visipaque. Of course, an unproven (and much disputed) theory can never support an establishment or superiority claim. The undisputed evidence is that the actual mechanism for the cause of CIN is still not known.

Lanham Act does not demand such a rigorous finding. Nonetheless, although not dispositive, the FDA agrees with the Court's findings in numerous letters sent to GEH, including one as recent as March 21, 2005, where it states that the results of the NEPHRIC study cannot be extrapolated to CM other than Omnipaque in GEH advertising. (P1894.)

To lay the foundation for Bracco's claims, and GEH's defenses, the parties first presented background clinical evidence at trial. The following pertains to such evidence: randomization in a clinical trial increases its reliability;[14] a primary endpoint is a clinically relevant endpoint around which a study is designed;[15] studies may also have secondary endpoints, which are of interest but are deemed to be of less importance to the study investigators;[16] a MA is a statistical combination of results from multiple studies;[17] a p-value is a statistical measure that provides a general estimate of the probability that two tested clinical strategies are different;[18] furthermore, the probability that two treatments are different can be roughly estimated as 1 minus the p-value.[19]

After laying a foundation for generalized information regarding the interpretation of medical studies, the parties presented specific clinical evidence in connection with GEH's claim that Visipaque is less nephrotoxic than other LOCM. Changes in renal function are commonly measured

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[14] 30 T 139:17-140:16, 145:20-147:12.

[15] 30 T 172:14-22; 37 T 102:11-21; Harrison T 12:17-13:2; 5 T 85:7-13.

[16] 37 T 104:3-13.

[17] D249 at A450900.

[18] See generally, 30 T 189:3-9; 11 T 93:4-21.

[19] For example, a p-value of 0.06 represents a roughly 94% probability (1 minus 0.06 = 0.94 or 94%) that the two treatments are different. See generally, 30 T 185-186.

by serum creatinine ("SCr").[20] Dr. Peter Aspelin, an M.D, Ph.D., a professor of medicine in Stockholm,[21] and the author of NEPHRIC, testified that CIN is commonly defined as an increase in SCr up to 3 days of 0.5 mg/dL, 25%, or both,[22] and that rises in SCr after 3 days may be due to factors other than administration of CM.[23] Bracco disputes this definition of CIN; it contends that rises in SCr after three days are significant. The Court need not determine the clinical significance of CIN after three days because while I find that such data is relevant to the weight given to a study's conclusions, here I find that the use of either definition would not make the underlying study unreliable.

Nonetheless, it is undisputed that patients with both renal insufficiency (RI) and diabetes are at a higher risk for developing CIN, than patients with only RI or only diabetes.[24] In addition, Dr. Harold I. Feldman, an expert in internal medicine and nephrology, proffered by GEH, testified that patients with only diabetes have a lower risk than patients with only RI[25] and that greater contrast volume increases a patient's risk of CIN,[26] while N-acetylcysteine (NAC) or sodium bicarbonate

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[20] 30 T 87:18-88:18, 88:25-89:21; 1 T 184:13-23.

[21] 10 T 117:25-121:8.

[22] 10 T 21:21-24, 144:19-146:13; 30 T 95:6-96:13, 101:5-15, 103:13-104:24; 1 T 185:19-186:25; 4 T 64:3-65:9; D107 at B476793; P3039 at B781784; Spinazzi, 9/06 T 63:3-65:21; D594 at 1.

[23] 10 T 47:6-17, 146:15-147:14; 30 T 104:19-106:7; 32 T 216:2-25.

[24] 10 T 14:13-15:8; 30 T 107:21-109:25, 112:6-114:20; 3 T 89:10-15; D98A at 553; D94 at 492; D2392 at 1-2.

[25] 30 T 112:6-115:2; 20 T 217:1-6; D2392 at 1-2; D904 at B149234.

[26] 30 T 116:23-117:11; D2392 at 2.

may reduce CIN.[27] Furthermore, it was established at trial, through expert testimony and exhibits, that there is a scientifically reasonable and widely held belief in the medical community that LOCM are less nephrotoxic than HOCM due to the reduced osmolality of LOCM.[28] This belief is also shared by Bracco.[29] As to LOCM, Dr. Feldman testified at trial, that as of February 2003, there was little evidence of differences in nephrotoxicity between Omnipaque and Isovue.[30] Bracco's Dr. Spinazzi testified, and published to his peers, that as of the date NEPHRIC was published, it was believed that all nonionic LOCM performed similarly even though he qualified the testimony as not being supported by "evidence in the field."[31] Notwithstanding the prevailing belief in the field, the FDA found it to be misleading for GEH to advertise, based on the NEPHRIC results (comparing Visipaque to one LOCM, Omnipaque), that "Visipaque is safer than other conventional non-ionic contrast media." (P1894). This implies that the FDA did not believe that there was sufficient support to conclude that all LOCM perform similarly. Thus, the FDA questioned, based on the NEPHRIC study, claims of Visipaque superiority over all LOCM as opposed to merely the LOCM tested in NEPHRIC.

GEH relies on several scientific studies to support its claim that Visipaque is less nephrotoxic than other LOCM, and hence has a better renal safety profile, but primarily, GEH relies on the

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[27] 30 T 116:14-19; 4 T 85:10-86:11, 100:13-101:15.

[28] 10 T 124:11-125:11; 30 T 123:23-125:5; D2268 at Table 3; 1 T 130:17-23; 4 T 105:25-106:20; D2269 at 386-87.

[29] D1411-T at B266402.

[30] 30 T 110:16-111:10, 194:10-196:4; 31 T 111:8-112:1.

[31] Spinazzi 09/06 T 56:10-60:14; D594 at 1-2; D236 at 9.

Chalmers and NEPHRIC studies. Chalmers, first published in 1999, was a randomized head-to-head trial of Visipaque (iodixanol) and Omnipaque (iohexol) adminstered to patients with RI.[32] It showed Visipaque to be less nephrotoxic than Omnipaque.[33] NEPHRIC was a double-blind, randomized, multi-center, head-to-head trial comparing the nephrotoxicity of Visipaque and Omnipaque in patients with RI and diabetes.[34] Dr. Aspelin was the principal investigator ("PI") for NEPHRIC.[35] He has nearly 200 published papers and is a peer-reviewer for several journals.[36] Dr. Aspelin was not a consultant for GEH and was not paid for his work on the NEPHRIC study, however, he did receive input from GEH regarding the formulation of the language used in his conclusions in NEPHRIC and indeed, GEH was the financial sponsor for the study.[37] NEPHRIC reported that Visipaque was less nephrotoxic and caused 11 times less CIN than the studied CM, Omnipaque.[38]

Dr. Aspelin had overall responsibility for, and final authority over, the content of NEPHRIC.[39] The other NEPHRIC authors, including Dr. Berg (a renal physiology expert)

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[32] D228A, 30 T 133:25-134:16.

[33] D228A at Table 2, 30 T 136:4-9; 37 T 133:18-21, 134:15-135:2; 32 T 96:3-98:19.

[34] D94, D894; 30 T 136:22-137:12, 138:15-139:7; 3 T 88:12-23, 102:15-22.

[35] D94; D894 at 2; 10 T 9:11-17.

[36] Id.

[37] 10 T 8:5-8; 18:8-17; 130:14-131:14.

[38] D94 at 493-95; D894 at A322520; 10 T 153:16-155:17; P 1526 at A292614; 30 T 176:17-177:5, 184:18-186:15, 187:13-191:5; 3 T 90:3-23.

[39] 10 T 17:5-17, 76:18-77:20, 81:18-85:22, 87:1-14, 133:9-14; 20 T 6:2-17, 33:17-34:1.

contributed to and approved the contents of the article.[40] While the results of the NEPHRIC study, which was a head-to-head comparison of Omnipaque and Visipaque, provide reasonable scientific support for the claim that Visipaque performs better than Omnipaque in high risk patients, it does not support the claim that Visipaque performs better than all LOCM for that patient group.[41] See infra pp.132-39. Other studies in the field and referred to at trial will be reviewed below.

a. The RECOVER Study

RECOVER was a randomized blinded head-to-head clinical trial, published in 2006, comparing the nephrotoxicity of Visipaque and Hexabrix (ionic low osmolar CM) in patients with RI.[42] It showed that Visipaque was less nephrotoxic and caused less CIN than Hexabrix.[43] Neither party, Bracco nor GEH, was involved in the study or publication of RECOVER.[44] Bracco alleges that RECOVER is unreliable due to a discrepancy with an earlier published abstract. However, the RECOVER authors explained in a published letter to the editors that the published results in the Journal of the American College of Cardiology (herein "JACC") were accurate, and that the results reported in the earlier abstract were based on preliminary data.[45] Accordingly, the Court finds this

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[40] D94; 10 T 76:18-77:1, 80:2-20, 132:20-133:14.

[41] D94 at 498; 10 T 77:24-78:23, 80:2-23; 30 T 194:10-195:17.

[42] D1990; 31 T 4:20-5:15.

[43] D1990 at 926-27, Figure 2; 31 T 27:11-28:2; 4 T 74:10-14, 75:8-76:10.

[44] D1990 at FN on 924; 31 T 6:12-20.

[45] D2381 at 1669; D 421 at 1669; D839 at 32A; 31 T 34:20-25, 38:22-39:12, 42:9-45:7, 57:5-58:1.

study to support the contention that Visipaque is less nephrotoxic than Hexabrix.

b. The Jingwei Study

Jingwei was a head-to-head clinical trial, also published in 2006, comparing the nephrotoxicity of Visipaque and Isovue in patients undergoing percutaneous cardiac intervention ("PCI").[46] It showed that Visipaque caused smaller SCr elevations.[47] Nonetheless, there was no clinically significant difference in the occurrence of CIN. The record does not indicate any involvement by GEH or Bracco in the Jingwei study.

c. The McCullough Meta-Analysis ("MA")

The McCullough Meta-Analysis ("MA"), published in 2006, used patient level data from head-to-head randomized intra-arterial clinical trials gathered from a GEH patient database.[48] Dr. Peter McCullough, a consultant for GEH, and co-authors had control over the MA.[49] McCullough found that Visipaque was less nephrotoxic than LOCM in: (i) all risk level patients; (ii) patients with RI; and (iii) patients with RI and diabetes.[50] Bracco's expert, Dr. Lee Jen Wei, re-analyzed the MA and confirmed that Visipaque causes less CIN than the LOCM analyzed in the study using the CIN definition chosen by McCullough.[51] However, as Wei cogently and significantly pointed out during

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[46] P4047; 3 T 156:21-158:1.

[47] P4047 at abstract; 3 T 156:21-158:1.

[48] 31 T 48:10-25, 53:17-54:25; 34 T 33:5-36:12.

[49] D265A; 34 T 28:22-30:24.

[50] D265A at Figure 2, Table 4; 34 T 40:3-47:4, 49:6-50:18; 31 T 51:2-12, 56:5-12.

[51] 12 T 54:17-55:14, 57:1-11.

his testimony, the McCullough MA was comprised of 16 studies, 9 of which were Omnipaque and 7 of which were non-Omnipaque LOCM. Isovue only represented 1 of the 16 studies. Dr. Wei concluded through statistical analysis, and the Court finds his testimony credible and persuasive, that when the non-Omnipaque studies were compared to Visipaque there was no statistically significant difference in CIN and that the nine Omnipaque studies skewed the results. Therefore, the Court does not find the McCullough Meta Analysis Study reliable for the claim that Visipaque ("IOCM") causes less CIN than all LOCM.

d. The VALOR trial

The VALOR study, sponsored by GEH, was an head-to-head clinical trial comparing the nephrotoxicity of Visipaque and Optiray, and allowed for the discretionary administration of N-acetylcysteine ("NAC").[52] Following a protocol specified interim analysis, it was determined that patients receiving NAC had more CIN.[53] Thus, enrollment was suspended and then terminated.[54] A manuscript reporting on VALOR was submitted for publication in 2007.[55] The incidence of CIN was lower with Visipaque than Optiray, and Visipaque caused a lower maximum percentage change in SCr from the baseline.[56] However, the study concluded that there was no statistically significant

[52] 20 T 25:18-27:5; P4288 at A456428; P4290 at A456460.

[53] 20 T 40:6-23, 42:24-45:6; P 224 at A148468-71; P 281.

[54] 20 T 40:6-23, 42:24-45:6.

[55] 20 T 64:14-19, 73:17-74:3; P4288; P4290.

[56] P3366 at Rudnick 0026-0027; 3 T 141:16-142:13; 20 T 61:19-63:4, 84:1-7.

difference in the incidence of CIN between the two CM tested; therefore no reliable conclusions can be drawn from this study as to Visipaque's renal superiority.

e. The IMPACT article

IMPACT was a study sponsored by Bracco and completed in 2006.[57] It was not a prospective study, but combined secondary data from two previously completed Bracco studies, INVICTA and VIRPACT, that were designed to study image quality, not CIN.[58] The post-hoc combination of data from two studies was not disclosed in the manuscript and is not an accepted practice in the scientific community.[59] Although Dr. Feldman testified that IMPACT does not contradict the conclusions of NEPHRIC because of the different patient sample groups, IMPACT does come to the conclusion that Visipaque and Isovue performed similarly and had similar renal safety profiles in patients at elevated risk for CIN.[60]

f. The CARE Study

CARE was another Bracco sponsored study[61] comparing Visipaque and Isovue. CARE was published in May 2007, and, prior to that, was not available to GEH.[62] All patients received sodium bicarbonate according to a protocol from the Merten study, which showed that sodium bicarbonate

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[57] Spinazzi 9/06 T 8:18-23; 3 T 33:4-6; D236.

[58] D236 at B723074; 3 T 36:8-38:5, 40:3-20, 42:17-21, 45:1-7; Spinazzi 9/06 T 18:14-19:9; 83:12-84:2.

[59] P3724; 3 T 45:16-46:2.

[60] 31 T 90:21-93:7; 94:15-96:2; 21 T 76:5-77:9; D241 at B585169.

[61] Spinazzi 9/06 T 8:2-23; 21 T 43:12-21; D912.

[62] P 4076.

reduced CIN when used with Isovue.[63] Merten concluded that sodium bicarbonate inhibited the negative effects of hyperosmolar stress caused by LOCM such as Isovue.[64] At the time the CARE protocol was finalized, there was no significant evidence that bicarbonate was beneficial when used with an iso-osmolar agent like Visipaque.[65] Dr. Feldman testified that CARE does not speak to the relative nephrotoxicity of Visipaque and Isovue without use of bicarbonate and does not contradict Chalmers, NEPHRIC, RECOVER, Jingwei, or the McCullough MA.[66] That is true, however, the Court finds this study's findings probative because its results indicate no statistically signifcant difference in CIN between Isovue with sodium bicarbonate and Visipaque with sodium bicarbonate.

g. The Sharma Pooled Analysis, Solomon Systematic Review and Solomon/DuMouchel articles are biased and methodologically flawed

The Sharma Pooled Analysis (D 262A) was drafted in-house by Bracco and was based upon a prior article by Dr. Alberto Spinazzi, Bracco's senior vice-president responsible for medical and regulatory programs.[67] Bracco performed the statistical analysis[68] and paid Dr. Samin K. Sharma,

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[63] D387 at 2328; D912 at 10, 15; 3 T 166:13-167:14; 4 T 85:10-14; 31 T 59:23-60:22, 67:2-68:2, 69:15-70:24, 74:13-77:25; D2102 at 18; 4 T 109:8-110:23; D2298 at B089532-33; 21 T 50:18-54:13.

[64] D387 at 2333; 31 T 79:12-80:6.

[65] 4 T 98:22-103:6; 31 T 85:20-86:14, 87:16-23.

[66] 31 T 61:9-63:5, 84:16-85:5, 102:12-103:21; P 2556 at B367123 (Sharma discussing "confounding effect of drug pre-medication"); 21 T 37:3-39:2.

[67] 20 T 219:23-228:1; D594; D1864 at B412842; 21 T 19:15-22:17, 30:20-33:6, 35:7-12; D 1438 at B404824, B404832; D1356; D1860 at B412734; D262A, 4 T 54:1-55:4.

[68] D1356, 1595, 1864; 20 T 219:23-228:1; 21 T 30:20-33:6; D1860 at B412734.

a doctor at Mount Sinai School of Medicine, $50,000 for his costs associated with the article.[69] Bracco also drafted the Solomon Systematic Review (D 107) and paid Dr. Richard J. Solomon, a specialist in internal medicine and nephrology and an expert proffered by Bracco, $30,000 for his involvement.[70] Together with Dr. Solomon, Bracco published an abstract of its review, but without data from Chalmers to "strengthen the argument" of equivalency between Isovue and Visipaque.[71] Bracco and Dr. Spinazzi were intimately involved in drafting the Solomon/DuMouchel article (D 222).[72] Because of methodological flaws, the Court finds that no reasonable conclusions on the relative nephrotoxicity of Visipaque, Omnipaque and Isovue can be drawn from the Sharma, Solomon Systematic Review or Solomon/DuMouchel articles.[73] Bracco's expert, Dr. Isabel Elaine Allen, attempted to validate the Solomon Systematic Review, but her analysis was plagued by errors.[74] The reported CIN rates in both Solomon and Sharma were in fact lower for Visipaque than for both Isovue[75] and Omnipaque,[76] although the difference in the rate of CIN between Visipaque and Isovue was not statistically significant. There was a statistically significant difference in the rate

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[69] D1356; 20 T 221:22-225:6.

[70] D1847; 4 T 25:20-29:7, 32:8-40:15; D105 at B272551; 4 T 42:11-44:14.

[71] 4 T 32:8-40:15, 44:15-53:20; D1847; D1850; P2818.

[72] Spinazzi 9/06 T 238:21-239:19.

[73] 11 T 155:18-157:14; 31 T 101:2-102:17, 104:1-106:3, 115:7-21, 124:12-131:18; 32 T 4:16-10:23, 12:3-11, 13:16-17:24.

[74] 11 T 119:23-123:12, 124:9-126:8.

[75] D262A at 391; D107 at Table 3; 4 T 69:15-70:1.

[76] D262A at 391; D107 at Table 3; 4 T 66:20-67:8, 68:3-16; 31 T 121:13-122:14.

of CIN between Visipaque and Omnipaque, and furthermore a statistically significant difference between Isovue and Omnipaque; Visipaque and Isovue performed better than Omnipaque overall.

h. The NEHPRIC Study

The NEPHRIC study, reported in the NEJM (P2467), compared Visipaque and Omnipaque head-to-head, but stated in its conclusion that "[n]ephropathy induced by contrast medium may be less likely to develop in high-risk patients when iodixanol [(an iso-osmolar contrast medium)] is used rather than a low-osmolar, nonionic contrast medium." Bracco assails the reliability of the NEPHRIC study by contending: (1) it was not designed to test whether osmolality is responsible for CIN (e.g., 20 T 6) and therefore cannot support the conclusion that Visipaque performs better than all LOCM in connection with renal function and CIN; (2) it has never been repeated in an AWC study; (3) it does not provide any support for the conclusion that Visipaque is as good as or better than LOCM with prophylactics;[77] and (4) it does not represent the weight of scientific evidence. (P2467; 3 T 89-90).

In addition, Bracco avers, through the testimony of Dr. Solomon, that Table IV of the NEPHRIC article, which purports to present results from other studies, is inaccurate and misleading because it incorrectly reports the results of those studies. (3 T 126-31; P3148, 37, 2053, 2386, 2390). Bracco also alleges that Table IV is inaccurate and misleading because it does not report the allegedly contradictory results of GEH's NEPHRIC II study;[78] but NEPHRIC II was not completed

[77]None of the cited studies used pretreatments. P2467:916-7.

[78]During this litigation, GEH concluded a study called "NEPHRIC II," in which it compared Visipaque and Isovue head-to-head. The study results are not part of the record in this case and the Court declines to draw an inference, as Bracco requests, that this study showed that Isovue was at least equivalent to Visipaque.

prior to the publication of the original NEPHRIC article and therefore could not have an impact on the reliability of the Table IV charts when published. Additionally, any such allegations as to the results of the NEPHRIC II study are speculative and it is improper for the Court to draw any inferences in the absence of its production.

According to Bracco there are several additional flaws inherent in NEPHRIC which make it unreliable:

- Primary outcome flaw. The record indicates that Nephric's primary endpoint – mean peak change in serum creatinine – is not a reliable metric, although it is used in the article and GEH's ads (e.g., the 11 times better assertion). (33 T 207) (Feldman). P4288:437 ("unknown clinical significance"), P200 (p3, FDA rejects Nephric's mean peak change endpoint); see also P1540 (definition of clinically significant)

- Omitting of key results. The NEJM article does not report the 25% rise in serum-creatinine results (P44, P4144, P1887; D2039T), which GEH added to make the study more comparable to the Chalmers study and to provide a more rigorous test for CIN. Id.; 3 T 90-99. Instead, the article falsely states that the secondary endpoints were significantly better. (P2467:913). GEH's marketing director was aware of this unreported data (e.g., P1951:131 (declining to provide the 25% results in Spain)) and he permitted the article to falsely report that all of the secondary outcomes showed a statistically significant (defined as $p<0.05$) difference between Visipaque and Omnipaque[79]

- Hydration flaws. Inadequate hydration was described by a GEH doctor as one of the "greatest weaknesses of the study" but it was not acknowledged in the article or any ad. (P530:148, 20 T 25; 3 T 101-105).

- Baseline and other population flaws. The patients in the Omnipaque group had worse baseline values (P207-08, P979, P1887, P48, P49; 3 T 119-120; 20 T 35), which greatly increases the chance of getting CIN. Id. The patient groups also had other differences that were never analyzed together. Id.; 3 T

[79] GEH avers that CIN at seven days is not relevant, but this contention is debated amongst the scientific community. (E.g., P1877:878, P2201:147-48, P1891:286).

105-109,112-117. Furthermore, since there was no standard hydration, and hydration changes baseline values to an unknown extent, there is no way to know the correct values and thus there was no way to accurately calculate mean peak change or CIN. P823, P4250; 20 T 39.

- Improper manipulation. While the study was ongoing, and in violation of the protocol and proper practice, GEH took secret and forbidden peeks at the data looking for trends, and even changed the study endpoints and stopped the study early in response.[80] E.g., P562:821 (found "Mean of max day 2 and 3: 20% (25% for Omnipaque and 15% for Visipaque)" to compare treatment arms before study completion), 1882:966 ("The statistician thought the data [from the two treatment arms] looked equal in both CrCl groups."); 11 T 20-26, 43-44, 71-75; D2039T ("pretend", "plausibility will not increase"), 2339, 2440. These types of unplanned interim analyses (defined by D2340:42 and D2339:34 as any comparison of treatment arms prior to completion) and secret attempt to "fix" the study midstream makes the trial non-prospective. P830; 20 T 28-33, 11 T 14-44, 70-71; P130. When a NEJM reviewer asked whether there was an interim analysis (P1869, 46), GEH and the authors replied there was none, and then amended the article to falsely say there was none. (P68; 20 T 17-18).

- Hidden duration of diabetes flaw. Duration of diabetes may be a predictor of CIN (P 4377:29K; 34 T 57-62). GEH found that the statistically significant higher duration of diabetes in the Omnipaque patients may explain the results, independent of the CM, making the conclusion of the article unreliable. GEH did not reveal these results to the public. (P49, P967, P4364, P4364T, P4365, P4365T; 20 T 33-34).

- Misrepresentative conclusion and manuscript. GEH's marketing director provided input to the NEJM article to try to make it misleading, and then celebrated the final version's obscuring of the limitation of the results of the study to Omnipaque and its overly broad and unsupportable conclusion. P1519, P1534, P1535, P4210 (admitted to only show input), P1532, P4208, P1672, P1873 (conclusion same as TCT abstract), P1876, P4208; 6 T 87-89, 13 T 62-71; see also P480.

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[80] For example, in a 2/21/01 email, the clinical research managers were informed that "we surprisingly see that some patients have max increase in serum creatinine on day 7 (not within day 3 as expected)." P213; 20 T 20-22. Shortly thereafter, GEH amended the protocol to add day 7 and other results as outcomes. P44, 4144. In addition, on 9/13/01, with knowledge of the blinded results, GEH stopped the study early, before the full number of planned patients were enrolled. (11 T 31-33; P130, P550; 20 T 24).

(Pl.'s FOF ¶ 13). Taking into consideration that the study compares one LOCM (Omnipaque) with Visipaque, nonetheless, the Court does not find that the study's results are vitiated by the flaws identified by Bracco. In addition, the NEPHRIC study uses conservative language in its conclusion (e.g. - use of Visipaque "may" cause less CIN than "a" LOCM), which does not render the study unreliable merely because it only compared Visipaque and Omnipaque. As it pertains to GEH's advertising, however, the non-definitive language used in the NEPHRIC conclusion permits GEH to use it for the contention that Visipaque may be renally better than a LOCM (which in the context of the article, means better than Omnipaque), but only if GEH plainly identifies, in same size print (and not in footnoted material), that Omnipaque was the only LOCM compared and that the NEPHRIC findings are limited to the studied CM.[81] The NEPHRIC article cannot be used to claim that Visipaque has a superior renal safety profile to all or any other LOCM. Further, in regard to the claim that "Visipaque is as good as or better than LOCM with prophylactics," the Court finds that the results of the NEPHRIC study cannot reliably support such a conclusion because using a LOCM with prophylactics was not part of the results of the study and was only concluded through a MA.

Moreover, Bracco contends that reliance on NEPHRIC is unreasonable because all other reliable clinical trials, reviews and MAs demonstrate no basis for a superiority claim of Visipaque over Isovue. Indeed, Bracco contends that all reported AWC clinical evidence and properly conducted MAs (e.g., Dr. Wei's unrebutted MA of GEH data) show no statistically significant

[81]In addition, if GEH uses the brand name "Visipaque" in its advertising, it must similarly refer to the studied CM, "Omnipaque," by its brand name and not by its clinical reference, iohexol.

difference between Visipaque over either Isovue or Optiray, whether given i.a. or i.v.[82] (1 T -4 T,11-12). Bracco also contends that for seven years prior to the NEPHRIC campaign, no doctors had ever observed that Visipaque caused less CIN, Id., and that GEH's internal hidden data, never mentioned in its ads, also show no renal superiority for Visipaque.[83] GEH reported to its representatives that the studies provide valid and reliable information and that anecdotal experiences are not reliable in making CIN comparisons. (P260:413; 13 T 72-74).

In further support of its claim for false advertising, Bracco also relies on FDA findings which declined to approve a renal superiority claim for Visipaque. The FDA has repeatedly found (e.g., in the years 1996, 2001, 2005) that there is inadequate support to make renal superiority claims for Visipaque. (E.g., P596, P457, P585, P200, P816, P1894; 7 T 54-56; 14 T 41-57; 15 T 25-37, 38-39, 43-48). Furthermore, in 2001, GEH submitted the proposed NEPHRIC study to the FDA with proposed superiority claims. (P200, P199, P4205, P816, P556, P818, P1542, P264B, P271, P1670,

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[82]Bracco cites to the following, e.g., 2 T -4 T; Care (Solomon D.; P4434 (Solomon Dec.); P4076); Impact (P3724); Verow (D528); Carraro (P2361, P3790); Fischbach (P2644); Kolehmainen (P3017); Rao/Newhouse (P2933); Chalmers (P405; D228A); Solomon (P2818); Dr. Allen's "unrebutted" repetition of Solomon and further confirming MA (11 T 82-115); Solomon/DuMouchel (P3167); Sharma (P2556); Dr. Wei's unrebutted MA of GEH data (11 T, 12 T); Kay (P478); Katholi (P3782); Haight (P2362): Briguori I (P2650); Baker (P2626); Rudnick (P3735, 2940); Briguori II (P3003); Sandler and letters to the editor (P49; P1167); Consensus Panel (P2770); Tepel (P2789); Barrett (P2821); Liss (P2674); Bettman (P2819); CMS/Federal Gov't (P2672:660, P2555:105).

[83] E.g., VALOR showed no difference and no NAC toxicity (P833, 835, 891, 937, 931, 940, 266, 273 (admits insufficient scientific proof), 15 T 159; 16 T 131-32)); Visipaque MA (P1733, no difference in i.v.; 2203:154, no difference in i.v. and other conflicting results); Stevens MA (P1937); ECR MA (P2201:149-150, 2214, 2221, 2229, 2230, 2241; McCullough MA with table with LOCM identified (P2228:943) that was not displayed in final article; Verow CIN data (more CIN with Visipaque than Isovue, 12 T, not reported in P2356); Safety MA (P560); DXVD09 (P566, 567). 1 T -4 T.

P1543, P810, P972; 20 T 48-57; 14 T 57-62). The FDA again rejected GEH's proposed claims, requiring AWC clinical trials and rejecting NEPHRIC as an AWC clinical trial (e.g., "the current [NEPHRIC] protocol contained a number of sources of variability, which may confound the ability to clearly determine the effects of the drug on renal function"). (P200, 1542; 20 T 48-51).

As part of GEH's rebuttal to the assertion that its representations constituted false advertising, GEH relied on four studies: Chalmers, NEPHRIC, RECOVER and the McCullough MA. Bracco contends that flaws in these studies vitiate their results as follows: (a) Chalmers was not AWC (small and unblinded), showed no significant difference (there was total agreement that the 10% test is irrelevant), and even the authors concluded it was weak (3 T); (b) NEPHRIC is unreliable; (c) RECOVER only involves Hexabrix (an ionic agent), it showed no differences in certain CIN measures and it is unreliable (3 T; Solomon Dec; D1990; P3823); and (d) the McCullough MA is of limited value as demonstrated by Dr. Wei's unrebutted testimony (11 T -12 T) that the McCullough MA results were mostly due to Omnipaque (and not Isovue).[84] The Court finds that these studies' conclusions do not establish the proposition that Visipaque has renal superiority to all LOCM.

Turning specifically to the NEPHRIC study, despite certain flaws, there were significant reliable aspects. The Visipaque and Omnipaque groups in NEPHRIC were demographically comparable.[85] The requisite number of patients pursuant to the protocol were included.[86] All

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[84]GEH's attempt at trial to cull trends in the data using selective hindsight cannot support its establishment claims that rely on specifically cited studies that used defined levels of statistical significance. (P1894; Pl.'s FOF ¶¶ 3-10,22-24).

[85] 30 T 156:24-172:9; D894 at A322564; 10 T 91:6-22, 103:7-16, 166:24-167:18; 32 T 139:13-141:4, 142:18-143:22; 33 T 190:1-193:2, 219:11-12, 223:23-224:5; P 4365; 3 T 148:4-22; D904; 4 T 58:20-63:24.

patients had RI and met the inclusion criteria.[87] Also, the Court is not convinced that the use of NAC in 11 patients affected the viability of the NEPHRIC results.[88]

Furthermore, contrary to Bracco's assertion, no interim analysis, as that term is understood and defined by the scientific community, was performed during NEPHRIC.[89] ICH and FDA Guidelines for clinical trials, adopted by Bracco's expert Dr. Sanford Bolton (an expert in pharmaceutics, physical pharmacy and bio-statistics, as authoritative),[90] define an interim analysis as the unblinded comparison of treatment results.[91] During NEPHRIC, the results were not unblinded and treatment results were not compared.[92] ICH and FDA Guidelines acknowledge that a sponsor may, without impacting a study's validity, monitor the success of planned accrual targets

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[86] 10 T 29:10-20, 98:25-100:10, 138:23-141:10, 162:14-163:1; D2223 at 37 (61 patients required in each group, 70 planned to allow for dropouts); D94 at 493 (129 evaluable patients); 11 T 68:2-16.

[87] D94 at 492; 10 T 133:15-137:13; 3 T 89:10-15; 20 T 76:10-77:7; P208.

[88] D94 at 497; 30 T 174:12-20; 32 T 194:24-197:1, 199:12-200:8, 201:19-202:1.

[89] D94 at 493; 10 T 33:10-35:25, 116:18-117:11, 157:9-19; P 551 at 3; P562 at 3; 11 T 45:2-47:15, 48:8-24, 51:11-52:5, 52:13-65:8, 70:3-22; D2339 at 18, 34; D2340 at 2, 23, 42; 20 T 19:2-20:2, 20:20-23:6, 58:11-18, 59:25-61:8; 33 T 158:4-20, 167:9-168:7.

[90] 11 T 54:25-56:21.

[91] D2339 at 18, 34; D 2340 at 23, 42.

[92] 10 T 116:18-117:11, 157:9-19; 11 T 45:2-47:15, 48:8-24, 51:11-52:5, 52:13-54:24; 20 T 19:2-20:2, 20:20-23:6, 58:11-18, 59:25-61:8; 33 T 158:4-20, 167:9-168:7; P551 at 3; P562 at 3.

and the appropriateness of design assumptions.[93] Indeed, it is the sponsor's responsibility to do so.[94] Thus, GEH's monitoring of patient enrollment, sample size assumptions and overall (not separated into two treatment groups) SCr changes (e.g., Ps 562, 1882, 1883, 1884, 1885 1890, 1891), do not constitute interim analyses.[95]

As to Bracco's claim that GEH influenced the wording of the NEPHRIC study conclusion, the Court finds that GEH did have input. Nonetheless, Dr. Aspelin's first draft dated March 6, 2002, which was authored before GEH offered comments and before presentation of an abstract at the TCT conference, also included a conclusion applying NEPHRIC results to the class of LOCM.[96] [97] Further, Dr. Aspelin testified that he, his co-authors, and the New England Journal of Medicine editors believed in the scientific reasonableness of the conclusion.[98] All of this lends support to the reliability of the article, but combined with the chronic rejection by the FDA of its use for superiority advertising and the fact that the NEPHRIC article only compares one LOCM to Visipaque, it cannot

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[93] D2339 at 18, 34; D2340 at 23, 42.

[94] D2339 at 18; D2340 at 23.

[95] Bracco additionally contends that some secondary endpoints were not included in the published article. However, allegedly constrained by word limits, the authors made determinations as to the results to include. 10 T 148:20-149:12, 150:21-156:9; 30 T 190:22-191:5. Nonetheless, not all these secondary endpoints were supportive of the study's conclusions. D94; 10 T 150:21-153:2; 37 T 132:1-18; 30 T 190:1-13; D894 at A322520.

[96] P1875 at A32164;10 T 159:5-22; see also P1876; 10 T 75:9-23.

[97] P1875 at A321641 ("In conclusion, our results reveal a highly important clinical feature that patients at risk for developing CIN might significantly benefit from receiving iodixanol compared to other LOCM"); 10 T 159:5-22.

[98] 10 T 76:18-83:24.

be concluded from the study and the article that Visipaque is renally better than all LOCM. Indeed, this latter finding is also supported by the non-definitive language used in NEPHRIC's own conclusion that Visipaque ***MAY*** cause less CIN than ***A*** LOCM. Thus, the Court concludes that the NEPHRIC results do not support a claim of Visipaque renal superiority over all LOCM or any LOCM other than the one tested in that study (Omnipaque) because only one LOCM was compared, and because the NEPHRIC conclusion does not make an absolute claim of Visipaque renal superiority, hedging its findings with less than definitive language; NEPHRIC also does not support a conclusion that Visipaque has renal superiority over LOCM with prophylactics because the study did not compare any LOCM with prophylactics against Visipaque.

i. None of the Proffered Studies Demonstrate that all LOCM (including Isovue) without Prophylactics Cause the Same Rate of CIN

Bracco contends that P1937, an internal GEH document with MA results, shows differences in rates of CIN between LOCM and that as such, a head-to-head study with one LOCM cannot be extrapolated to other LOCM. GEH contends that this was not an analysis of relative CIN rates[99] and that published guidelines treat all LOCM, including Omnipaque and Isovue, as functionally interchangeable.[100] However, the Court finds that even though multiple CM are categorized together as LOCM, it does not mean that they have the same effect, or produce the same rate of CIN. The Court is not persuaded that all LOCM perform identically - multiple studies introduced in evidence

[99] P1937; 32 T 18:1-20:24.

[100] P2193 at A451448.

show that not all LOCM perform similarly nor do they produce the same rate of CIN. (See RECOVER, Jingwei, McCullough MA, VALOR, IMPACT and CARE).

3. GEH's Establishment Claims Of Non-Renal Superiority

GEH also disseminated establishment claims of cardiovascular system, pain, warmth, discomfort and patient movement superiority, and establishment claims that Visipaque, and iso-osmolar agents generally, are a superior class of drugs that lead to lower hospital, legal and patient care costs. The Court finds that these claims explicitly or implicitly assert that data from clinical studies show that Visipaque is superior to a LOCM or all LOCM and thus they are establishment claims. As with the renal establishment/superiority claims, these claims were: (a) designed to be disseminated (Pl.'s FOF ¶ 4); (b) shown to be effective by GEH's collective experience and marketing research (Pl.'s FOF ¶ 4); (c) disseminated by the GEH representatives (Pl.'s FOF ¶ 5); and (d) disseminated in various channels of communication.[101]

a. GEH's Non-Renal Cardiovascular Superiority Claims Are Not False And Misleading

Examples of the cardiovascular system establishment/superiority claims extracted from GEH's print media, sales calls records and CME-type presentations are:[102]

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[101] See additional examples of plans and instructions for (a) cardiovascular claims (P712, P1681:254, P1689, P2101:566; 7 T 43-52), (b) discomfort-type claims (P869:179, P1136:373, P632:455, P789;276), and (c) class/cost claims (P708:715, P789:275, P1012:720,722; 8 T165-75).

[102] See also P2161:388-89, P1013:789, P782:890, P779:695, P729:013, P2280:p8, P395:360, P409:948, P1868:137, P2283:p1, P373:070, P4171:p1, P4177:p1, P4089:619, P3654:508, P2047A:806, P2166:548, D945:425, P2561:032, P2291:p8, P2298:p11, P410:972, P3649:415, P3649A:415, P3890:246, P2281:p26, 29, P3831:637, P3890:238.2-39, 41, P2670:508, P3828:967-68, 976, P3829:032-33, 44, P2156:032-33, 44, P2157:203-04, 237-38, P3831:613-14, P2671:524, P3831:613, P3261:024, P2157:198, P2305:p6, P3114A:809, P3114B:811, P4089:440, P453, P510, P142:507, P520, P137:390, P2670:507, P510, P514, P3828:976;

- Press releases on website even during trial: "Abstract Shows Significantly Lower Incidence of [Major Adverse Cardiac Events or Major Adverse Clinical ("MACE")] Following [PCI] Using Visipaque Compared to Isovue.…" P2669:480, P3114H:857-58, P1893:940-41, P4151:p2; 7 T 69.

- CT brochures: "Nonionic Dimer Provides Reduced MACE …" P410:965, P3649:408, P3649A:408, D2324:117.

- Sales call records: "Visipaque doesn't increase heart rate or B/P like LOCM". P3682:Omni/38573, 4049:Omni/38573.

i. MACE

Bracco contends that GEH's cardiovascular claims are false because: (a) the studies do not support the claims (e.g., no superiority over all LOCM, i.a. results do not predict i.v. results, and any difference purportedly shown in studies was fleeting because the results for different contrast agents converge after 30 days); (b) there were allegedly omitted results and flaws that contradict the claims made in GEH's advertising; and (c) the studies GEH relies on (COURT and VICC) are unreliable. The following is a detailed analysis of Bracco's allegations beginning with the various promotional materials disseminated and moving on to the integrity of the COURT and VICC trials. Bracco's assertions, include: (1) the weight of the clinical evidence shows that Visipaque is not superior to all LOCM and definitely not superior to Isovue (Bracco concedes that ionic Hexabrix may be inferior); and (2) there has never been one AWC clinical study (let alone two, done the same way with the same drug) showing that Visipaque is superior to a LOCM with regard to MACE.

D2324:124. Bracco also alleges that the COURT article (P2561) is a false ad or promotion. Additional sales call records are P3689L-2, P3689M-2, P3493G.

1. FDA findings

Referencing a series of letters dating back to 1996, Bracco argues that the FDA found no support for GEH to make cardiovascular superiority claims. (E.g., P596, P457, P588, P585, P82; 15 T 25-39, 43-44). Nonetheless, some of these letters pre-date the COURT trial (circa 2000) and all pre-date the VICC trial (circa 2005) and since that time, new evidence has come to light. Thus, the Court finds these FDA letters are neither dispositive, nor highly probative as to whether GEH's advertising was literally false regarding its claims of the incidence of MACE. See infra pp 129-32.

2. COURT Study as Reported by GEH

Bracco asserts that GEH reported false information from the COURT study. (P2561). According to Bracco the study is limited to: (a) a comparison between Visipaque and ionic Hexabrix; (b) the patients studied ("extrapolation of these results to [a stable] population is not possible" (P2561), and the reported results were not consistent with the results from the less sick patients in the VIP study, see discussion infra at p. 41-42, (P71)); and (c) a fleeting difference in adverse events between the two drugs cumulatively at the 30 day point (something not mentioned in GEH's ads). (5 T 37-44). Bracco also asserts that the actual data, including data not disclosed by GEH, show that there were no differences between the drugs and the results were not reliable.[103]

[103] Specifically, Bracco points out: the study report (P2), containing the actual results available to GEH and the investigators, but never made public until the trial, shows that the article misrepresents several critical results, including: (a) the results of the blind and valid adjudications of the data, which showed that the results were due to procedural differences and not to the contrast agents (compare P2561, reporting a statistical difference due to CM, with P2:142-5, reporting no statistical difference due to CM and all statistical differences due to procedures; 19 T 33, 45-47; 23 T 155-157); (b) the fact that the CKMB measurements were unreliable (compare P2561:029) with P2:127; 19 T 31); and (c) a primary (within 30 day) outcome was falsely reported as a secondary outcome (compare P2561 Table 4 with P2:109-110, 122-23, 25; 19 T 27-30), to minimize the effect of the negative result.

GEH responds by contending that COURT was a randomized head-to-head clinical trial comparing Visipaque and a LOCM, Hexabrix, in 856 high risk patients undergoing Percutaneous Transluminal Coronary Angioplasty ("PTCA").[104] Dr. Davidson was the principal investigator ("PI") and helped design and run it.[105] Dr. Kevin Harrison, the PI of the Bracco sponsored VICC trial, was also an investigator for COURT.[106] The primary endpoint of COURT was in-hospital MACE.[107] The in-hospital period is most relevant because MACE events caused from CM, as opposed to those caused by other factors, tend to cluster in the first few days.[108] The Visipaque group had less in-hospital MACE than Hexabrix (5.4% vs. 9.5%) and fewer myocardial infractions ("MIs") (2.0% vs. 4.4%).[109] The incidence of MACE at 30 days favored Visipaque (9.1% vs. 13.4%).[110] Dr. Kern, a Bracco expert, agreed that COURT showed that "the incidence of [MACE] and major angiographic complications are reduced in high risk patients undergoing coronary interventions with Visipaque compared with Hexabrix."[111] MACE events in COURT were adjudicated in a blinded manner by

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[104] D903 at 2172-73; 5 T 38:5-39:9; 23 T 32:22-36:16; Harrison T 10:11-17.

[105] 23 T 28:3-16.

[106] D903 at 2172; 23 T 28:23-29:14, 31:23-32:8.

[107] D903 at 2173, Table 3; 23 T 36:17-38:15; 19 T 35:21-36:2.

[108] 23 T 42:14-25; 19 T 35:21-37:15.

[109] D903 at 2173; Harrison T 13:4-11; 23 T 39:13-42:3; 5 T 40:8-41:3.

[110] D903 at 2175; 23 T 43:1-22.

[111] 5 T 42:14-21.

the authors.[112] I need not find whether the COURT results could support a conclusion that MACE is related to osmolality,[113] because the conclusion in COURT only stated that Visipaque causes less MACE than Hexabrix in high risk patients undergoing coronary intervention.[114] The Court finds that, despite the qualms referenced by Bracco, the COURT study is sufficiently reliable to permit one to conclude with reasonable certainty that it established a cardiovascular superiority claim for Visipaque over Hexabrix for use in high risk patients undergoing coronary intervention. COURT does not, however, suppot such a conclusion as to any LOCM other than Hexabrix.

3. VICC study

The Bracco-sponsored VICC trial compared Isovue to Visipaque. (P2326, P3909). However, this study has never been published in a peer-reviewed journal[115] and Bracco contends that it was poorly designed and unreliable based on several flaws, including: (a) its crossover effect and lack of a washout period, (23 T 122-124)); (b) its failure to uniformly measure CK-MB (23 T 126-127); (c) its side effect; and (d) the adjudicators' failure to follow the rules on calculating CK-MB change (P3912:654). D1441; 5 T 44-67; 25 T 121-44; 33 T (Spinazzi). The Court finds that these concerns, whether in isolation, or in conjunction, do not make the study so unreliable as

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[112] 19 T 10:13-11:22, 16:3-16.

[113] D903 at 2176; 23 T 48:24-52:22; 5 T 111:6-18.

[114] 23 T 51:23-52:22; 5 T 107:6-11; D1720 at B323667 ("COURT elevated Visipaque over Hexabrix, but still left the monomers below both, in PCI only.").

[115]The fact that the VICC study has never been published in its entirety does not bear on this Court's determination of whether VICC is reliable. Nonetheless, an abstract of the VICC trial was presented to the American Heart Association and published in 2003. P362; 5 T 55:7-12. While the manuscript was submitted for publication to the journal Circulation, following comments, it was never re-submitted. 23 T 67:15-19; 23 T 68:19-24.

to render it unsupportable for the conclusions stated therein. The results of the trial show that Visipaque had statistically significant less incidence of in-hospital MACE than Isovue.

GEH correctly avers that VICC was a Bracco sponsored head-to-head randomized trial comparing Visipaque and Isovue in 1276 patients at mixed risk levels for MACE.[116] Dr. Harrison was the PI.[117] Drs. Charles Davidson and Morten Kern were co-investigators.[118] The idea for the VICC trial came from Duke University, which approached Bracco for support.[119] The evidence reveals that Bracco agreed to sponsor it and then tried to minimize publication of any negative results.[120] The primary endpoint of VICC was the incidence of MACE in the earlier of the first two days following contrast administration, or until hospital discharge.[121] The VICC protocol specified CK-MB for the primary diagnosis of non-Q-wave MIs.[122] CK-MB are commonly used in clinical practice for such diagnosis.[123] Visipaque caused less in-hospital MACE than Isovue (4.8% vs. 9.0%), including less in-hospital non-Q-wave MIs (3.4% vs. 7.5%), which the study concluded was

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[116] P3632; 23 T 66:19-67:12; 5 T 45:9-22, 46:5-13.

[117] Harrison T 8:2-7.

[118] P3632; 23 T 59:22-60:19, 70:19-23; D2437 at Davidson 001507.

[119] 33 T 6:3-14; D2440.

[120] D1433 at B365439 ("it was decided to sponsor the study to have more leverage and control in case of questionable results."); 33 T 14:16-17:22, 30:2-5, 34:8-35:16; D2424 at B416880-81.

[121] P3632, D2437 at Davidson 001513-14, D1296 at B002475; 23 T 76:17-77:1.

[122] D1296 at B002500; 23 T 74:10-12, 74:19-76:16.

[123] 5 T 120:13-121:22; Harrison T 47:21-23, 49:3-10; 23 T 75:22-76:16; D1956 at B404402 ("The investigators believed in the clinical significance of CK-MB elevations…but not of critical elevations of troponins…"); 33 T 73:17-75:7, 75:22-25, 76:12-77:8, 78:9-78:18.

significant for treatment.[124] At 30 days there were significantly fewer non-Q-wave MIs with Visipaque.[125] The periods of 0-7, 2-7, and 2-30 day MACE were included as secondary endpoints in VICC, but are not as clinically relevant as in-hospital MACE.[126] There was also no significant difference in repeat PCIs of the target vessel, i.e., the vessel treated at the time of procedure.[127] Repeat PCIs of non-target vessels are unlikely to be related to the effects of CM.[128] The Court finds that it is scientifically reasonable to conclude from VICC that (1) Visipaque is associated with significantly less in-hospital MACE than Isovue;[129] and (2) Visipaque is associated with fewer non-Q-wave MIs than Isovue.[130] The primary results of VICC and COURT are essentially the same.[131] VICC confirmed the findings of COURT, extended it to a different comparative agent, and was a more contemporary study based on the practice having changed, i.e., use of more stents and the use of more IIB/IIIA inhibitors.[132] Dr. Kern testified that the lack of a washout period in VICC makes

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[124] P3632; 5 T 47:25-48:17; D2437 at Davidson 001535; 23 T 76:17-77:24; Harrison T 20:9-19.

[125] 23 T 77:25-78:14; P 3632; D2437 at Davidson 001508; Harrison T 73:21-24; 37 T 135:10-137:9.

[126] Harrison T 80:23-81:18.

[127] 23 T 37:5-11, 79:11-80:23; D2437 at Davidson 001523.

[128] 5 T 54:19-22; 23 T 78:15-80:24.

[129] 23 T 76:17-77:24, 85:3-9; P3632; D2437 at Davidson 001517-18; 5 T 47:23-48:17.

[130] 23 T 77:14-24, 78:8-14; 33 T 37:20-38:3; P3632; D2437 at Davidson 001517-18; Harrison T 73:21-74:5.

[131] 23 T 80:25-81:15.

[132] 23 T 80:25-81:15; 85:10-21.

the data difficult to interpret, but Dr. Harrison disagreed; he testified that it does not affect interpretability of the data.[133] In addition, Dr. Davidson testified that he did make sure that the patients in his portion of the VICC trial who underwent a diagnostic procedure got the same drug as in the interventional procedure, thus eliminating a crossover or a washout effect. (23 T 122:24-123:14). Furthermore, he found that Visipaque performed better than Isovue whether it was the same contrast agent being used in the procedures or whether there was contamination from another contrast agent. (23 T 123:18-124). Further, Dr. Kern signed the published abstract that did not mention the washout issue[134] and approved the protocol in conjunction with his colleagues.[135] The testimony reveals that Bracco believed VICC favored Visipaque, and thus would damage Isovue in the market. As a result, Bracco sought to contain damage by re-analyzing the data, seeking to undermine the validity of unfavorable results, and pressuring Dr. Harrison regarding the contents of the abstract and manuscript.[136] The Court finds that the VICC study is sufficiently reliable to permit one to conclude with reasonable certainty that Visipaque causes less in-hospital MACE than Isovue for patients undergoing PCI within the initial 48 hours after the procedure.

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[133] Harrison T 91:9-94:13; see also 23 T 81:16-83:16.

[134] P3632; 5 T 55:7-14, 111:19-22; 71:22-24.

[135] 5 T 111:23-112:14.

[136] 33 T 22:4-23:17, 25:9-26:7, 50:6-54:4; 55:18-62:23; 66:5-19; D 173; D 1433 at B365440; D 1439 at B408147,49-50; D 1823; D 1879 at B377869; D 1955; D 2105; D 2438; D 2439 at B401684.

4. The VIP Trial

The Court finds that VIP, a study published in 2000, that compared Visipaque and Hexabrix in low risk patients,[137] does not undermine the conclusions of COURT or negate its findings regarding high risk patients. However, VIP's conclusion that there is no statistically significant difference between Visipaque and Hexabrix in low risk patients with regard to MACE,[138] militates against any finding that Visipaque performs better than this low-osmolar contrast agent with regard to MACE in that patient group. Furthermore, since no other studies have focused on Visipaque and any other LOCM to confirm the incidence of MACE in low risk patients, there is no basis to assert any Visipaque superiority claims for MACE in low risk patients.

ii. Hemodynamic Effects

Bracco contends that GEH has not rebutted Bracco's evidence that iso-osmolality and Visipaque are not superior over Isovue or other non-ionic LOCM for heart rate, blood pressure, ECG, LVEDP and other cardiovascular effects as shown by Dr. Kern and VIP (P71), IMPACT (P2799), Sutton I (P3770), Sutton II (P3855), Verow (P2356), Manninen (P3846), Palmers (P3847), and Klow (3844), or that iso-osmolality does not cause less red blood cell deformity than LOCM. 5 T (Kern); P27, P34, P41; 2 T (Katzberg). Moreover, GEH's internal data also shows no superiority: DXVPRC01 (P1705); DXVD09 (P220:931). (5 T 76; 2 T 58-60).

Bracco contends that GEH's rebuttal ignored Bracco's proofs and relied on excerpts from three articles that are not cited in the ads in issue and that cannot support the scope of its claims: the Bergstra Article does not attribute the LVEDP difference seen between Omnipaque and Visipaque

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[137] D812; 23 T 55:2-56:4.

[138] 23 T 58:13-59:7.

to osmolality differences (D814:222) and the Soiva and Murdock articles did not involve Visipaque (D2249; D2377). In fact, Soiva, finding significant differences between LOCM, showed that LOCM cannot be considered as a uniform group. Here, GEH incorrectly contends that there is a good basis to conclude, from clinical trials, that Visipaque causes fewer and milder hemodynamic effects (e.g., heart rate changes) than LOCM[139] and that LOCM are all similar in this regard.[140] The Court finds that these conclusions are neither adequately supported nor reliably based upon the studies GEH cites.

b. GEH's non-renal discomfort-type claims

Examples of the discomfort-type (i.e., claiming less pain, warmth, discomfort or patient movement or designed for such) establishment/superiority claims extracted from GEH's print media, sales calls records and CME-type presentations are:[141]

- Website, brochures and CMEs: "[Visipaque] offers significantly better comfort to the patient…" P2508:767A, P2511C:781A, P4163:767A, P4166C:781A.
- CT brochures: "Less chance of extravasation-related complications — including pain, discomfort…when used:" "Less chance of patient discomfort…when used in:" "High

[139] D814 at 314; 23 T 85:25-88:4; 91:2-92:3; P28 at 93 (abstract conclusion); P2193 at A451436 ("some effects such as hypotension and tachycardia, are clearly related to hypertonicity."); P3028 at B781498; P3846 at 370 (conclusion); P 3852 at 614 (abstract conclusion).

[140] D2249; D2377; 5 T 107:6-11; 23 T 88:5-92:3.

[141] See also D945:430, P141:490, P2505:757A, P2511A:774A, P4155A:737, P4160:757A, P4166A:774A, P446:640-41, P729:013, P2280:p10, P395:362, P409:950, P3118A:865; P1868:134, P147, P161, P3448A:p2, P3114E:837, P2279:p5, 7, P3114G:856, P2157:214, P2161:388, P2183:980, P2184:998, P2311:p5, P2170A:739, P2170B:743, P3118B:863, P4236:716, P2171:751, P4243:241, P389:011, P779:695, P782:890, P1013:789, P2287:p1, P2288:p1, P2289:p3, P2293:p1, P2295:p1, P2296:p1, P2297:p1, P2284:p2, P374:073, P375:074, P3828:930, P3261:3012, P3829:037, P2156:037; D2334:p3, D4089:453, D142:520, D137:390. Additional sales call records are P3689L-3, P3689M-3, P3493H.

concentration", "High-rate injections", "Multiple procedures", "High-speed procedures." P410:966.

- Sales call records: "She asked why use Vis Shared theory isosmolar, less fluid shifts and thus less pt discomfort, movement and need to rescan...." P2312:A650688, P4049:A650688.

GEH makes claims that Visipaque is superior to LOCM because it provides less pain, heat, and discomfort and that these benefits are due to its iso-osmolality. Bracco contends that these claims are false and misleading because: (a) the studies do not support the claims (e.g., no superiority over all LOCM, i.a. results do not predict i.v. results, no difference in movement ever shown); (b) omitted results and flaws contradict the statements; and (c) the weight of the clinical evidence is that Visipaque is not superior to all LOCM and definitely not superior to Isovue. There may be a benefit in heat sensation that is sometimes described as pain in peripheral angiography, but that has never been proven and peripheral angiography is a de minimus use of CM. (1% today, 2 T 91; 29 T 158-159). GEH's own Dr. Anthony Nicholson, an interventional radiologist, testified that GEH's claims were too broad because any benefit of Visipaque is limited to direct local injections in small vessels, a limitation found in none of GEH's advertising claims. (Id.) In addition, there has never been one AWC clinical study that was repeated and supports the claim that Visipaque is superior to a LOCM (or all LOCM) in a manner claimed by GEH. Furthermore, Bracco contends that the FDA found there was no support to make discomfort-type superiority claims for Visipaque. (E.g., P596, 457, 588, 585, 82; 15 T 25-39, 43-44). At most, the FDA permits GEH to make a very limited and inconclusive statement about a trend that is not a superiority claim. (14 T 66).

There have been eleven studies showing no difference in patient movement and no reliable study showing a difference in patient movement. GEH's attempt to show a difference (DXV071)

was a failure so GEH did not make great effort to release the results. (P557).[142] Furthermore, data from unpublished studies showed no consistent differences in pain, discomfort or movement: GEH MA (P549); DXV071 (P557); DXVA001 (P220:930); DXASG001 (P220:930); DXVD11 (P220:932); 2 T. Bracco asserts that Dr. Michael Rappeport's survey demonstrated that the claim, Visipaque is superior regarding pain "compared to LOCM", is understood by an overwhelming proportion of customers to claim superiority to all LOCM. (Pl.'s FOF ¶ 18). However the Court is excluding Dr. Rappeport's survey for its inherent unreliability. See infra p. 90. In response to the Rappeport survey, GEH proffered Dr. Nicholson who presented several studies asserting differences in pain or discomfort (nothing on patient movement) but none compared Visipaque to all LOCM or even one LOCM in an AWC study that was ever repeated. (See 29 T).

Conversely, GEH avers that CM can cause pain, discomfort or heat upon injection, and that this aspect of patient comfort is clinically relevant.[143] GEH also contends that Visipaque causes less pain, discomfort and warmth than LOCM, including Isovue, in certain procedures,[144] and that this

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[142] Dr. Katzberg showed that the studies by Manke (P3845), Verow (P3853), Justesen (P3843), Pugh (P3848), Manninen (P3846), Conroy (P848), Sundgren (P3851), Tveit (P3852), Fishbach (P2644), Klow (P3844) and Palmers (P3847) showed no efficacy differences, and therefore no patient movement (or significant pain and discomfort that would affect movement and efficacy) differences between Visipaque and LOCM. (E.g., 2 T 91-105). GEH presented no rebuttal.

[143] 29 T 81:19-84:8, 127:17-128:23, 164:20-165:20, D2264 at 12 (left column); D519 at 208 (conclusion).

[144] 29 T 86:21-87:2, 88:13-90:9; D2264; D511; 29 T 98:19-99:24; D197; 29 T 100:20-102:14; D519; 29 T 102:15-104:4; D2248; 29 T 104:25-107:5; D 2261; 29 T 107:6-109:17; D2271; 29 T 109:18-111:1; D517; 29 T 111:2-113:18; D527; 29 T 113:19-115:11; D785A; 29 T 116:24-117:24; 2 T 178:12-15; 3 T 11:11-18.

difference is clinically relevant.[145] No study has shown Isovue to cause less pain than Visipaque.[146] Bracco acknowledged that there is less pain with Visipaque than Isovue in peripheral angiography procedures.[147] Bracco's expert, Dr. Katzberg, acknowledged the same.[148] Furthermore, GEH's expert, Dr. Nicholson, could not substantiate by a reasonable degree of scientific certainty, based on the studies, that any claim of Visipaque superior regarding pain extended beyond peripheral angiography procedures.[149] Accordingly, the Court finds that GEH's claims of comfort superiority are only supported in regard to peripheral angiography procedures. Thus, GEH's broad assertions of superior patient comfort are not supported by the conclusions of the various studies it uses to bolster them and any such advertising must be limited to the procedures that were used in the studies.

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[145] 29 T 127:17-128:23, 164:17-165:20.

[146] 2 T 174:14-19.

[147] D1623; 3 T 5:13-6:18.

[148] 2 T 178:12-15; 3 T 11:11-18.

[149] On cross-examination, Dr. Nicholson admitted he did not consider the significant viscosity and hydrophilicity differences between the drugs, entitling his testimony to little weight. 29 T 54,181-182. He also admitted that many of the differences he had noted were actually not statistically significant, many of the differences only related to heat sensation (and not pain or discomfort), that he failed to reveal other data in favor of the LOCM (e.g., D527, 785A), and in all of the remaining studies the dose of Visipaque was much less than the dose of the comparison drug, which would necessarily lead to less pain and discomfort (studies show the higher the dose, the more the heat, pain or discomfort). 29 T 160-184. GEH's proofs did not generally relate to the studies cited in the claims and even when they arguably did, they did not and could not support the claims.

c. GEH's Osmolality Class/Cost Claims

Examples of the osmolality class and cost establishment/superiority claims extracted from GEH's print media, sales calls records and CME-type presentations are:[150]

- Website: "Isosmolar Visipaque. It's innovative in a class of its own." P2505:757A, 2511A:774A, 4155A:737, 4160:757A, 4166A:774A, 3448A:p2

- Diagrams/claims repeated in websites, brochures and CMEs: Showing "hyperosmolality" (i.e., osmolality higher than blood, like Isovue) leading to "altered morphology" of "erythrocytes" and "endothelial cells", ultimately leading to "discomfort", "warmth", "coldness" and "pain." P2508:766A, P2511C:781A, P4163:766A, P4166C:781A; see also P3114K:823, P2510:771A, P2508:763A, P2511C:779A, P4163:763A, P4165:771A, P4166C:779A, P2183:982, P2184:000, P2311:p4, P2298:p25, P4252:p3, P3828:929, P3261:011, P3829:036, P2156:036, P2157:212. Additional claims of less red blood cell effect of IOCM vs. LOCM can be found at: P2311:p5, P3710:p2, P2280:p5, P395:357, P409:945, P333:738, P410:960, P3649:403, P3649A:403, P436A:421, 27-28, P2298:p7, 13-14, P782:893, P2161:387, P2183:991, P2184:009, P4252:p12, P4174:p1, P3114J:821, P3210:934, 410:962, P3649:405, P3649A:405, P2510:772A, P2508:764A-65A, P2511C:780A, P4163:764A-65A, P4165:772A, P4166C:780A; D2324:114, D2334:p2, D2324:112

- Health Value brochure: "Isosmolar VISIPAQUE may reduce financial burden due to serious adverse events". P446:641, P649:665

- Sales call records: "Used the 'cost' story for Visi vs. LOCM....." P3682:Visi/154349, P4049:Visi/154349

These claims are based upon alleged renal, cardiovascular or discomfort-type superiority tied to osmolality (e.g., 6 T 94-99) or costs. Bracco asserts that they are false and misleading because

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[150] See also P390:125, P612:171, P2286:p5, P2300:p4, P137:384, P1450:108, P4180:p11, P2956:721, P2290:p1, P1448:899, P2962:234, P2298:p3, P2291:p6, P1868:156, P410:963, P2309, P1013:789, P782:890, P779:695, P2292:p1, P3831:638, P2307:p48, P4251:203,209, P3831:591, P2281:p30,46, P2307:p18, P3828:927, P3829:987,992, P3890:238.1, P2156:987,992, P2157:059, 063, 077, 197-98, 213, P2671:522, 28, P3261:023, 050, 053, P4247:179, P3834:924, P3709:402, P333:731, P775:350, P415:126, P1598:887, P766:281, P2730:066, P2291:p4-5, 12, P1363:744,P 436A:443, P2298:p27,36, P374:073, P1868:153, P333:749, P2671:523. Additional sales call records are P3689L-4, P3689M-4, P3493I, P3493L, P3435, P3689L-5, P3689M-5, P3493J.

(a) the studies (shown above) do not support the claims (e.g., no superiority over all LOCM, i.a. results do not predict i.v. results), and (b) omitted results and flaws contradict the claims. The Court finds that the weight of the clinical evidence does not show that Visipaque is superior to all LOCM nor does it show that it is superior over Isovue, except perhaps under limited circumstances for pain and in-hospital MACE for patients undergoing PCI. The FDA found that there was no support for making class/cost superiority claims for Visipaque. (E.g., P588, P585, P82; 15 T 33-39, 43-44). Furthermore, GEH's medical officer testified that while iso-osmolality is a chemical property of the final Visipaque formulation, it does not put the drug in a proper, formal class of drugs separate from LOCM by FDA standards. (16 T 186-187) ("IOCM and LOCM are not separate classes, Correct?" "That is true."). This is because the FDA classifies all iodinated contrast media the same. (Id.)

In addition, Bracco contends that GEH improperly advertised the role of osmolality in causing adverse events. GEH's documents give some indication that Visipaque has a much higher rate (5-7 times) of delayed adverse events than Isovue and other LOCM (e.g., P1948:947(1.4% v. 0.2%), P2133, P1169, P544, P557, P3860:167; 13 T 82-85) and thus it belies GEH's superiority claims in regard to Visipaque (and iso-osmolar Isovist, withdrawn for this reason).

In light of this data (P1169:703, P4240:670, P544), GEH countered with claims that there were an equal or lower number of adverse reactions. (E.g., P2291:054, 2305(Conclusion), 2309, 976, 2026, 2027, 2286; 15 T 151-152). GEH also argues that Bracco's foreign affiliate and experts agree that osmolality is relevant to renal safety, cardiac safety, and pain/discomfort.[151] However, the Court does not attribute significant weight to these general assertions. Finally, Bracco asserts, and

[151] D2169; 3 T 16:3-5; P2818; 4 T 70:9-71:16; 5 T 111:6-18; 78:17-23; 3 T 11:11-18.

the Court agrees, that there is little evidence to support a claim of decreased costs using Visipaque. There is no support for GEH's claims that studies show that there is less patient care, hospital care or legal liability costs for Visipaque versus all the LOCM or even one LOCM.[152] The only way to make such a cost inference is by associating the cost of treating additional instances of MACE and CIN to higher overall cost, but since the Court has not made such a finding with regard to CIN, the only viable means of advertising lower cost is through less incidence of MACE for patients undergoing PCI within the 48 hours after the procedure.

4. Additional Evidence Regarding Dissemination

In addition to the proofs cited above, dissemination of allegedly false claims was confirmed by the testimony of Mr. Scott Kerachsky, Director of Marketing for GEH Healthcare, North America, (15 T 100-142), Dr. Peter McCullough (34 T 160-165), and stipulations by GEH. GEH representatives are instructed to present printed materials a section at a time, by pointing to specific parts, and not as a whole. (E.g., 15 T 116, 172-175; P2100:530, 2098).

But, in his testimony, Mr. Kerachsky also elaborated on the impact of GEH's various levels of approval mechanisms over promotional materials and their dissemination. Specifically, Mr. Kerachsky identified four levels of approval, medical, regulatory, marketing, and legal, whose responsibility it is to ensure that the clinical data provides support for proposed promotional

[152]In this regard, Bracco also asserts that GEH's Omnipaque claims are false. First, GEH obscures the fact that Omnipaque is a comparator in NEPHRIC (e.g., P1534; 6 T 99-101), by referring to it by its generic name, (16 T 70-71). In addition, GEH falsely promotes Omnipaque as "The Gold Standard," established by clinical studies as "minimizing risk," "optimizing image quality," and "maximizing cost efficiency," without any support and with contradictory clinical evidence, as shown above. (E.g., P3946, 1559:003). However, the Court finds that GEH's designation of Omnipaque as the "Gold Standard" is merely inactionable puffery.

materials. (15 T 86, 90). Mr. Kerachsky also testified that every piece of promotional material used by GEH's sales force was approved by medical, regulatory, marketing, and legal. (15 T 83, 86, 90). In fact, Mr. Kerachsky himself reviewed prospective promotional materials from a marketing prospective, mindful of FDA regulatory issues and possible conflicts with the underlying clinical data. (15 T 93, 95, 125). For example, with respect to NEPHRIC, Mr. Kerachsky testified that marketing "clarified, just to be extra careful, that it was iohexol" which was studied. (15 T 125).

For the time period covered by GEH's sales call record production (i.e., Sept. 2003-2005), Bracco asserts that at least 87% of GEH's representatives delivered GEH's clinical superiority claims. (17 T 102,107; 18 T 25-34, 40, 42-43; P3493M, 3922, 4049; D2004). While Bracco asserts that at least 82.5% of GEH's sales call records with substantive communications show the delivery of GEH's clinical superiority claims to customers, the Court finds this number to be grossly inflated based upon its own evaluation of the records and expert testimony; nonetheless, some instances of false messages are supported by the record. (See also 17 T 102, 107; 18 T 25-34, 40, 42-43; P3922, 4049; D2004).

GEH argues that Bracco has grossly mischaracterized the number of actionable sales call notes and promotional materials, specifically because of flaws in Mr. Russell's testimony. For example, Mr. Russell could not identify the basis for his testimony that certain GEH promotional materials contain pain/discomfort superiority claims.[153] Mr. Russell improperly categorized: (1) accurate discussions of the NEPHRIC study,[154] and (2) a Visipaque logo as renal superiority

[153] 18 T 19:3-15; P 2285.

[154] 18 T 7:21-10:2.

claims.[155] Mr. Russell could not identify the basis for his categorization of GEH promotional materials, including a specific piece containing the statement "Is your contrast media this close to plasma?" as cardiac superiority claims.[156] Mr. Russell improperly categorized statements, including "Currently, there is no health care common procedural code to delineate iso-osmolar contrast agents such as Visipaque from low-osmolar contrast media LOCM," as class claims.[157] Mr. Russell improperly categorized statements in GEH promotional material, including a piece that expressly states that medical personnel should consider taking prophylactic measures to reduce the risk of CIN, as promotion of "the lack of pretreatments and emergency use without renal function testing."[158] Nonetheless, a number of the sales call notes reviewed by this Court do indicate that certain members of the GEH sales force were using the NEPHRIC study's conclusion to make superiority claims.

In addition, GEH argues that Mr. Russell's analysis of sales call notes is unreliable because of the allegation that Mr. Russell's compilation of allegedly improper sales call entries was compiled by Bracco's counsel[159] and was widely over-inclusive. The compilation was created from 314,468 GEH sales call notes produced in this case.[160] For example, Mr. Russell improperly categorized

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[155] 18 T 10:7-11:4; P 2303.

[156] 18 T 11:16-18:15; P3710; P 2283.

[157] 18 T 22:3-25:4; P2285; P 2297.

[158] P390 at A221124, 129, 130, 132; 17 T 132:13-135:13, 138:5-14.

[159] 18 T 26:2-7, 29:7-16.

[160] D2004.

entries that reference only the word, "NEPHRIC," as being "on-message."[161] Also many included notes were duplicative.[162] In addition, GEH states that Mr. Russell's compilation improperly categorized sales call notes as (1) renal superiority messages; (2) cardiac superiority messages; and (3) evidence of the application of Visipaque "leverage." Indeed, Mr. Russell admitted that there was no reason that innocuous sales call entries such as "Discussed use of Visi for high risk patients"; "Told him about Visi for the coronary"; and "Thanked Dr. Vogel on the lead to move forward to bundle a LOCM and MRI contrast deal," were included in the above categories, respectively.[163]

GEH argues that due to the lack of standards employed, Mr. Russell's compilations are inflated and unreliable.[164] The Court argues that Mr. Russell's opinions as to the percentage of "on-message" sales call notes and representatives who made them are greatly inflated.[165] Nonetheless, the Court has had the opportunity to review the sales call notes and disagrees with GEH that the Court should only review sales call notes that mention Isovue as follows: (1) 284 notes that mentioned Isovue; (2) only 38 where Isovue was mentioned and a superiority claim that could arguably be construed from the note; and (3) 1,251 notes from a single GEH sales representative (Chad Chaney) who entered substantially the same comment for numerous notes.[166] I find that

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[161] 18 T 33:22-34:4.

[162] 18 T 33:1-6.

[163] 18 T 34:5-41:18; P3493-F at 74, 228; 18 T 41:21-43:19; P3493-G at 4, 8; 18 T 44:2-46:18; P3493-K at 3, 5, 7.

[164] 18 T 33:1-6; 33:22-46:18.

[165] 18 T 27:2-46:18.

[166] P3493 F-L; P 3689L-M.

focusing on the subset of sales call notes that explicitly mention Isovue would understate of the number of sales calls that improperly made Visipaque superiority claims over all LOCM. GEH's claim that Visipaque is better than all LOCM or a LOCM, without identifying the one LOCM compared, is what makes its advertising campaign problematic; a sales call need not mention Isovue specifically. In sum, Bracco's position that any advertisement which references NEPHRIC is false is incorrect and thus results in an over-inclusive determination; conversely, GEH's position that only those advertisements which compare or mention Isovue may be improper is under-inclusive.

5. Evidence Concerning Materiality

The evidence of materiality includes:

- The repetition of certain unsupported claims by GEH's sales and marketing teams.
- The substance of the claims (e.g., CIN and other clinical data), which cannot be anecdotally observed with reliability (e.g., P260:413; 5 T 28-29).
- The type of claims – i.e., drug safety, which GEH's own observations (7 T 178) and market research showed were the most effective in converting sales (E.g., P100-102, 104-106, 196:573-580, 1400, 1436, 1716:739, 2038, 2112).
- The limited evidence that it will take several years for Bracco to recover from GEH's false claims once they are stopped (17 T 117-118; 21 T 110-122).

These few examples, when considered in conjunction, demonstrate that GEH's false advertising claims appear material to a consumer's purchasing decision. Moreover, because I find that some of GEH's claims are literally false, as stated infra p. 143-45, there is a presumption of materiality and deception.

6. Harm, Damages And Other Remedies

a. Causation For Bracco's Losses

i. GEH's Testimony and Business Records

Numerous GEH witnesses conceded that Visipaque renal safety claims drove substantial sales increases which came, in significant part, at Bracco's expense. GEH's President, Dan Peters, testified that GEH enjoyed a dramatic sales increase after the publication of NEPHRIC, primarily due to GEH's renal safety message. (6 T 103; see also 7 T 94-95; P2461, 1892:925-6). He acknowledged that GEH's renal message had a "large impact" on the "whole market" while GEH tried to "minimize [Nephric's] negative impact on Omnipaque." (6 T 59-60, 100). GEH's Vice President of Sales, Don Quinn, confirmed that the "NEPHRIC data coupled with a very consistent targeted marketing campaign has propelled demand for Visipaque to new heights." (8 T 124-125; P849:934). He further admitted that GEH used NEPHRIC to convert competitive business, including Isovue accounts.[167] Mr. Quinn agreed that GEH set out to increase Visipaque's market share through an "aggressive sales and marketing effort" and that there "[a]bsolutely" was a connection between that effort and these increases.[168] In addition, GEH's global brand manager, Mr. Paul Gehris, admitted that GEH saw "very good share growth since the NEPHRIC" that was "driven by awareness of the data and the perceived differentiation." (13 T 77-80, 14-19; P1694:022). However, it remains that out of the entire GEH ad campaign relating to Visipaque, only a small fraction of the disseminated messages were indeed false. Most were proper and were backed up by the underlying scientific studies that they reference. Therefore, a causal connection cannot be made by a sales trend alone; the accurate touting of favorable results of reliable scientific studies plays too

[167] 8 T 122-123, 136-46, 177-178; 9 T 51-53, 128-130; 16 T 80-81; 7 T 156-157; P1365:776, 781, 1175:485, 100, 101, 104, 105, 106, 1021, 1004:042-3, 691, 694A.

[168] 8 T 82-84, 99-100; 9 T 6-9, 86-88; P849:943, 869:167,177, 2101:558-9, 2098:437, 1163:533, 1169:702.

much of a significant part in this case to determine that the limited number of false ads disseminated are the cause of Bracco's lost profits.

GEH sales representatives also gave testimony relating to GEH's renal superiority claims. GEH's representative salesperson, Mr. Murray, testified during his deposition that in general, when talking with customers about high risk patients, he discusses that the NEPHRIC study shows that Visipaque has a better renal profile than traditional LOCM. (See 16 T 84:4-11). However, when a question relating to that statement was posed to Mr. Murray at trial, Mr. Murray clarified his statement to mean that "when we were talking about NEPHRIC and the traditional LOCM, we were talking about [] Omnipaque." Id. 14-17. In fact, Mr. Murray testified that as a sales representatives "he tr[ied] to talk about Omnipaque and Visipaque."[169] While it is difficult for the Court determine what was actually communicated to the customers, based on Mr. Murray's testimony, some of this sales calls' messages may be construed as misleading, especially when Mr. Murray did not qualify or specifically identity Ominipaque as being the traditional LOCM. Nonetheless, the Court finds in its review of the sales call notes that the instances of sales reps making such misleading statements were limited. Importantly, the majority of GEH's messages were in fact true and properly relied on reliable scientific studies to support them.

GEH admitted that Visipaque's premium price resulted from its "clinical differentiation" messages. Mr. Quinn testified that customers "absolutely" had to believe Visipaque provided patient benefits to pay the price premium.[170] The 2004 Marketing Plan states that "based upon its clinical

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[169] 16 T 81-95, 8-9, 71-75. See also P400, 418, 387:433-34, 1608:074-5.

[170] 8 T 144, 125-126, 168; P849:937, 480:667. Visipaque is priced 2-3 times higher than Isovue. 18 T 124-125; P2070, 1912, 2687, 2715, 4271:tabs19-20.

differentiation … a significant price premium has been placed on Visipaque when compared to low osmolar products."[171] Mr. Gehris admitted the clinical differentiation strategy drove Visipaque's premium price. (13 T 14-19; P1436:616,622,635). However, this was in large part a result of the underlying studies and GEH's promotion of their results.

Quotes from GEH business records relating to GEH's claims of renal differentiation include, for example:

- "The objective ... to increase market share ... will be accomplished strategically by clinically differentiating Isosmolar Visipaque from all other LOCM products…." (P849:932; 8 T 123-124).

- "The Nephric success stories continue to come in with the majority of new dollars coming from competitive LOCM products." (P1311)

- "Sales performance reflects strong continued efforts in all markets to communicate NEPHRIC results and Visipaque clinical differentiation message.... Sales reports continue to highlight customer acceptance of these messages and adoption of Visipaque use in patients at risk of CIN." (P1157:744)

- "2005 is projected to be the 3rd consecutive year of very aggressive growth.... The NEPHRIC data, coupled with a very consistent and targeted marketing campaign ... has propelled demand for Visipaque to new heights."[172]

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[171] P854:937. See also 8 T 105, 162-167, 18 T 144; P869:180, 1362:720, 1012:719-22,711-6, 1178:677-80, 1341:467, 659, 785.

[172] P2098:426-429,437-40,442-3,446, 869:167-8,172-4,177,180,187-8, 854:931-9, 942-6,950-1, 2098:442, 2101:536,558-9; 16 T 46-48; P1145, 1147, 1265, 1266, 1269, 1584:788,790, 2112:779, 1677:102, 875:287, 2008, 1312, 1579:261-62,269; 15 T 170-176; P1014:871, 1017:292, 1309, 1311, 3944, 712, 1699:713, 1475:303, 2005:851, 1365:772, 1398:030,035, 1155:701, 1600:985-6, 1610, 1919:667, 1476:355, 661:935, 1579:262, 1473:287, 1474:296, 1561:015-17, 2019:509.

Because the NEPHRIC study itself concluded that Visipaque *may* perform better than *a LOCM*, and that conclusion accurately reports the study's findings, GEH's internal documents which advocate differentiation of Visipaque from other LOCM did not lead to a false message so long as GEH actually disseminated an accurate portrayal of the NEPHRIC results and did not extrapolate them beyond the limited comparison of Visipaque and Omnipaque. However, to the extent that GEH did not so limit its comparison and message, it would result in a false message.

ii. Sales Trends

In the LOCM market, three players (GEH, Bracco and Tyco) control 97% of the market, with Tyco's share almost entirely due to the Premier GPO. (P849:881; 8 T 123 (Quinn), 18 T 114 (Malackowski), 21 T 91-92 (Medici)). The Court finds that, outside of the Premier GPO (which is not part of Bracco's damages claim), the LOCM market effectively is a two-player market. This finding is reinforced by the undisputed facts of record that Bracco and GEH were effectively the only two competitors for the Novation, Consorta and Kaiser contracts (as discussed below). Mr. Medici testified both parties' market shares were stable but "changed dramatically" after the NEPHRIC article was published and its subsequent marketing, with GEH's sales increasing and Bracco's decreasing. (21 T 93, 97, 103-104, 110-113). Mr. Peters agreed that initially Visipaque had grown only gradually but "grew very well after the NEPHRIC study, yes." (6 T 44).[173]

iii. The Parties' Surveys

[173] Mr. Peters did not "remember anything out of the ordinary" besides NEPHRIC contributing to Visipaque's growth. 6 T 72.

The Court is excluding both Bracco's survey expert, Dr. Rappeport, as well as GEH's survey expert, Dr. Ericksen. However, Mr. Quinn, GEH's Vice President of Sales, in an email to GEH officials, announced the results of an informal study of physicians and their feedback regarding the NEPHRIC article, including the "top 3 messages that excite physicians to action," "Safety in patient with creatine above 1.5," "Less Nephropathy" and "Isosmolar Visipaque is 11 times less likely to cause renal failure."[174] In this case, each of these general statements may be part of a true advertising campaign, but only if they plainly describe the circumstances of the underlying studies, e.g. type of patients tested, and the actual products that were tested (and not in small footnoted material); GEH may not extrapolate these findings to CM which were not compared in these studies.

iv. Bracco's Harm and Response

Mr. Medici and Dr. Spinazzi testified that Bracco expended substantial resources, including spending millions of dollars, responding to the effects of GEH's allegedly false claims – e.g., responding to purportedly deceived customers; responsive advertising; sponsorship of the Sharma, Solomon and Solomon/DuMouchel papers; and two head-to-head Visipaque versus Isovue studies (CARE and IMPACT). (E.g., 20 T 108-149; 21 T 99-110). Bracco alleges that GEH's false ads caused Bracco and Isovue to lose significant reputation and goodwill. (Id.) However, Bracco's complaints about spending additional funds to sponsor studies verifying its product's efficacy cannot all be laid at the feet of GEH. Bracco and GEH are the primary players in the field of CM and thus, fiercely compete against each other in the marketplace, obviously target each other, and look to tout their own products whenever possible. Indeed, as shown during the course of the trial, by way of

[174] P696; 9 T 35-36. See also 13 T 27-28, 55-60; 15 T 181-184; P1716:739, 1742:968-71, 196:573-580, 1700:821, 1400:059-62.

the sheer number of sponsored studies proffered by both parties over the years, in this business it appears to be commonplace, if not a necessary part of the industry, for companies to spend significant amounts of capital in support of scientific comparative studies to promote sales of their products. Moreover, the Court was surprised by the revelations that virtually every clinical trial, study, and resultant publication in this area was sponsored by GEH or Bracco. In some cases, the principal investigators were paid consultants to one of these companies. This has lead the Court to conclude, and lament, that there is little in the way of a truly independent clinical study in the CM market.

v. Anecdotal Evidence of Visipaque Superiority

GEH argues that customers also observed Visipaque's alleged superiority, anecdotally. However, GEH's medical department concluded that "spontaneous clinical observation cannot give any statistical evidence" and only head-to-head studies can determine renal safety. (P260:413; 13 T 72-74). GEH's clinical expert, Dr. Feldman, concurs, 35 T 118-120; P3738:P3, as does the Court. Consequently, the Court finds that anecdotal evidence does not impact the validity or invalidity of GEH's superiority claims, and cannot be used to bolster the claims.

vi. Visipaque Leverage.

GEH developed a "Visipaque Leverage" strategy to keep existing accounts and convert competitive accounts by (1) "penetrating" the account with Visipaque; and (2) "leveraging" a contract award by threatening to raise Visipaque prices if GEH lost the bid for its other products. The 2004 Visipaque, Omnipaque, and Omniscan Marketing Plans all prominently feature Visipaque

leverage.[175] Shortly after GEH developed its "VVAT" tool to illustrate Visipaque Leverage to its customers, it observed "several examples already of customers threatening to leave [GEH] ... that reconsider their decision once they understand the consequences of Visipaque price increase should they decide to leave [GEH] on other products." (P786:201, 470).

vii. The Novation Contract

In 2004, Novation issued an invitation to bid (ITB) for its Injectable CM (ICM) contract.[176] GEH, Bracco, Berlex Laboratories, Bristol-Myers Squibb, Guerbet, and Tyco Healthcare submitted bids.[177] Novation selected twelve members from Novation hospitals to comprise a Task Force ("TF") charged with assisting in the evaluations.[178] Its members were experienced with CM. Shortly before the TF's meeting at which it decided to award a separate technology contract for

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[175] P849:940 ("Visipaque penetration must be expanded significantly in competitive accounts especially in order to leverage it in a way that can pull through additional Amersham Health products"),879,994-5 ("Expand Visipaque usage, especially in competitive accounts so that it can be effectively leveraged to pull through other Amersham Health products"). See also P1341:469 ("Visipaque pricing should be used as a lever … If Visipaque is highly penetrated based on clinical superiority, this offers the highest level of competitive immunity"),473,483, 642:558, 650:683, 721, 1327, 693:396, 1420:648,650, 1679:161,170-1, 3493K (GEH sales call records regarding Visipaque Leverage), 1941:746; 8 T 117-122 (Quinn); 17 T 110-112 (Russell); 21 T 117-122 (Medici); 18 T 125-127, 143 (Malackowski); 38 T 81-87 (Stewart); P1676:088.

[176] Mr. Sweeney, Novation's second in command with overall responsibility for the bid, was deposed as Novation's Rule 30(b)(6) witness. P4078; Sweeney T 60:22-24, 61:10-13; 36 T 176:4-24.

[177] P4085 at Bracco/Nov 000103; 36 T 176:4-24.

[178] Sweeney T 96:25-99:22; P 4135 at Bracco/Nov 003620; Sweeney T 29:1-30:22, 32:12-33:6, 51:22-52:1, 66:6-67:15, 73:2-8, 84:6-85:7, 88:1-89:1; 36 T 176:25-180:22.

Visipaque, Novation provided the members with COURT, NEPHRIC, and VICC.[179] The TF recommended, and Novation awarded, a technology contract for Visipaque.[180]

At the technology meeting, a Novation representative presented the technology claims for three products. With respect to Visipaque, the representative "went over all of the clinical documentation and referenced the pre-reading. The consensus of the TF was that this contrast agent is unique and innovative and offers clinically proven incremental benefits over other products on the market. The TF believes Visipaque should be carved out and identified as innovative."[181] It is unknown which specific incremental benefits the TF considered or upon what specific information the TF relied in making its decision to carve Visipaque out of the ICM bid.[182] Generally, Novation asked the TF "to use [relevant] information along with their personal practical and own clinical experience to evaluate not only the bids but new technology submissions. And so it's [Novation's] belief that they do that."[183] It also asked the TF members "to do their own research within their institutions and talk to those clinicians who have further experience, and we expect them to represent that fairly in their decision-making process."[184] Novation saw no evidence that the TF relied on

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[179] P4094 at Bracco/Nov 3419, 3421-3435; P 4097; Sweeney T 298:23-300:3; 36 T 184:19-185:13.

[180] Sweeney T 300:5-301:19; P 4085 at Bracco/Nov 000102; P4097; 36 T 180:23-181:21, 184:2-186:12.

[181] P4132 at Bracco/Nov 003612; P 4085 at Bracco/Nov 000102; P4097; see also P4095.

[182] Sweeney T 300:25-301:19, 229:14-25, 302:3-20; 36 T 194:8-15.

[183] Sweeney T 301:16-19, 67:5-15, 132:25-133:17, 140:18-141:7, 164:12-165:20.

[184] Sweeney T 302:15-18; see also 36 T 193:18-194:7.

advertising in concluding that Visipaque offered clinical benefits.[185] Indeed, the stated conclusion of this experienced task force—that Visipaque offers "clinically proven" benefits—is itself evidence that experts in the field can reasonably conclude that Visipaque has advantages over other CM.

In April 2004, as a result of the technology award, Visipaque was carved out from the ICM contract decision process; the TF did not further consider Visipaque in analyzing either the non-financial or financial components of the ICM bids.[186] Even after Visipaque had been carved out, GEH received the highest scores from the TF with respect to all non-financial criteria (NFC).[187] Novation's contract development department evaluated the financial portions of the bids and scored each supplier with respect to the financial criteria (FC).[188] The bidder with the lowest ratio of FC score to NFC score has the low best bid.[189] Novation awarded a sole-source contract to GEH based upon its top score on the NFC and its low-best bid for an x-ray/CT and MR combined contract, and based upon the fact that it was the only qualified bidder on ultrasound.[190] The Novation TF appears to have based its evaluation of GEH's bid on personal experience, feedback from physician

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[185] Sweeney T 140:18-141:7, 301:21-302:1.

[186] Sweeney T 64:21-65:21, 213:10-15, 281:5-21, 293:21-295:1, 307:15-308:1, 311:17-19, 322:12-19; see also 36 T 180:25-181:21, 183:16-192:2.

[187] P 4083; P4084; P4085 at Bracco/Nov 000103; Sweeney T 295:3-12, 73:14-20, 92:24-93:6, 100:19-102:9,; 36 T 163:24-164:22, 195:1-198:5.

[188] Sweeney T 32:7-14, 75:4-22.

[189] Sweeney T 74:4-15, 75:10-13.

[190] P 4085 at Bracco/Nov 000103; P 4083 at Bracco/Nov 000094, Sweeney T 233:13-23, 303:19-304:22.

colleagues, clinical information, and the positive relationship Novation had with GEH.[191] It is impossible to determine how, if at all, the award decision would have been "different if in fact the council viewed Visipaque differently than [it] did," and had Visipaque not been carved out.[192] Ultimately, on March 1, 2005, Novation, a long-time customer of GEH, announced that GEH had won a sole-source contract for X-ray and MR CM. (P4118).[193]

As is usual in this market, all bidders, except GEH and Bracco, were eliminated early.[194] Novation identified presumptive winners using a formula Low Best Bid ("LBB") = FC/NFC. (P4126, 4083). The LBB results appear on a CT Decision Award Criterial Matrix ("DCAM"); MR DCAM; CT+MR DCAM; and Dual DCAM. (P4083). NFC scores were provided by the TF and FC scores were calculated "in-house" at Novation.[195] Bracco was the LBB for the CT DCAM and the Dual DCAM. Bracco was a very close second on the two other DCAMs:

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[191] Sweeney T 140:18-141:7; 36 T 197:7-198:5; see also Sweeney T 83:13-84:2, 84:4, 171:22-172:7, 199:13-200:16.

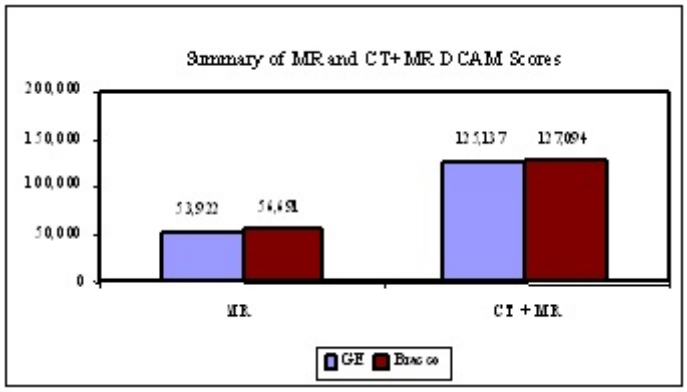
[192] P4085:101,109. Mr. Sweeney's purported "belief" that Visipaque would also have been carved out of the NFC is outweighed by all other evidence of record, which indicates that Visipaque was only carved out of the FC criteria; that Mr. Sweeney was not aware of any instructions to the TF to exclude consideration of Visipaque from the NFC; and that the TF was given express instructions to consider GEH's bid summary in scoring the NFC. Sw. 65-8, 123, 130-179, 210-211, 229-231, 236-237, 312-316, 322-323; P4094:436-7. GEH's GPO expert admitted that "common sense" would indicate that the TF *did* consider the Visipaque information in the bid summary. 36 T 218-219, generally 208-239; 37 T 21-23, 29-32.

[193] Sweeney T 41-2, 177; P4120, 4112.

[194] Sweeney T 94-9,102-6,233; P4085:103, 4083:094-5.

[195] Sweeney T 29-32,68-71,96-9,116,191; P4135:620, 4084.

(19 T 63; P4083; 37 T 44-45). This is because Bracco's FC scores were millions of dollars lower. (P4083; 37 T 38-40).



However, Bracco contends that if Visipaque had been included in the FC, Bracco would have been the lowest bidder for the CT+MR DCAM – by a margin of more than $13 million – and it would have therefore won both the CT and MR sole-source contracts.[196] Bracco further contends that GEH's allegedly false Visipaque claims almost certainly affected the NFC scores as well. GEH's NFC score was 138.2 points higher than Bracco's. (P4083, 4084; Sweeney T 316-7). Bracco would have won the CT+MR DCAM (and thus both contracts) if GEH's NFC score was only 15 points lower or, conversely, Bracco's 13 points higher (or if both changed by 7-8 points). (P4085:101,103; 19 T 80-81; Sweeney T 256). The Court does not, however, find that GEH's false advertising was a

[196] P4085:101,103; 19 T 67-71.

substantial factor in the TF's carve-out decision. GEH maintains that Novation's decision to renew its longstanding contract with GEH was not based on advertising, let alone GEH's alleged false advertising, noting that GEH and its predecessors had held a sole source contract with Novation since at least the late 1980s and Novation was generally satisfied with GEH products and services.[197] In fact, Bracco even acknowledged that it was extremely unlikely that Novation would award a contract to another supplier and gave itself a 0% chance of winning a sole source award because of GEH's strong relationship and history with Novation and the general satisfaction of Novation members with GEH products.[198] The Court finds this longstanding favorable business relationship highly probative of Novation's decision to continue awarding the bid to GEH.

The Court also finds that the NEPHRIC article itself was a substantial driver for Visipaque's special carve out, and that even if there was false advertising in GEH's ad campaign, it was not sufficient to be a material factor in this bid. The TF members and their colleagues were titled individuals chosen from the staff at various hospitals, who may have been exposed to GEH's Visipaque promotional campaign,[199] but who were also privy to the underlying studies supporting such contentions. GEH's pre-award sales call records on Novation member hospitals show the

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[197] D2178 at 82; D31 at B461508.

[198] D1373 at B117118, 20, 24-25; 28 T 62:10-70:1, 73:10-78:19, 88:13-93:9; D 2047 at B168239; D2202 at B116235 ("Amersham is going to be an extremely difficult incumbent to unseat. There is excellent product performance, acceptance, service and general comfort with the entire Amersham product line."); D2178 at 82; D31 at B461508 (Bracco felt there was "[n]o expectation of change [in Novation's contrast media contract] for 2006…"); D2199 at B502821; D2207 at B226890.

[199] P732 (Quinn/Smith memo instructing representatives to "drive home a win" at Novation by "conveying strong clinical differentiation messages"), P4049 (database containing sales call notes for TF hospital members and colleagues); 37 T 54.

limited dissemination of GEH's false superiority claims.[200] The Court finds that the offending sales call notes were too few to have a material impact on the award of the Novation contract nor were these sales calls made directly to any of the TF members participating in the decision. Although Bracco asserts that a few weeks before the carve out decision GEH met with the TF and again presented its Visipaque claims, the TF was still privy to the underlying studies and free to come to its own conclusions regarding Visipaque and its desirability as a CM.[201] More importantly, Bracco has not proffered evidence to show that any of the TF members were influenced by the ads as opposed to the underlying studies when they made their decisions.[202]

In fact, Novation gave the TF a 27-page summary of the "things ... viewed to be most important" from GEH's 300-page bid. Dan Sweeney, Vice President, Contract and Program Sales at Novation, testified that Novation provided the TF with GEH's bid summary to serve as the main reference to evaluate GEH's bid.[203] However, Mr. Sweeney could not testify what additional information the TF members considered except for their own personal experience in the medical field. (Sweeney T 66:9-23). Even if the TF only considered the bid summary, the Court finds that

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[200] See, e.g., Sales Calls Records, P2312 at A629955, 654950; A632476; Visi/93672; A623608; A627592, Omni/28079, A682435; Omni/67769; A660995; A670058; A637828, Visi/72736; A617748; A637355, 646585, Omni/28094, A682451; Omni/28303; A607435; A600371; A637302, 656303, 672542, Visi/66061; A618919; A637346, 646552, 682434; A611637; Visi/57817.

[201] P2161:391 ("Demonstrated to significantly reduce incidence of ... CIN"),388 ("Improves levels of patient comfort"),389-90("Demonstrated to significantly reduce ... MACE"), 4127, 4128:604, 4102, 4262; 37 T 56-57.

[202] Sweeney T 306:8-20, 118:14-24, 120:1-11; see also 36 T 142:6-143:4, 199:17-200:10.

[203] P4137; Sweeney T 65-8,130-43,313; P4078:032, 4085:102, 4084, 4133, 4134.

the bid summary does not claim Visipaque superiority to all LOCM. In response to the bid summary's inquiry as to clinical studies that evaluate the safety and efficacy of the proposed products, GEH cited to the NEPHRIC, COURT, and VICC studies. Specifically, GEH expounded on NEPHRIC's results as to renal safety, stating that "[i]n a comparison of VISIPAQUE vs. iohexol, VISIPAQUE was demonstrated to significantly reduce incidence of contrast-induced-nephropathy (CIN). . .and the conclusion was that nephropathy induced by contrast medium may be less likely to develop in high-risk patients when VISIPAQUE is used rather than the low-osmolar, non-ionic contrast medium." (P4137:6331) (emphasis added). In light of their experiences, the TF members should have known that iohexol is Omnipaque and that NEPHRIC's conclusions are limited to that comparison, given the language in the bid summary that Visipaque may be safer renally than "the low-osmolar, non-ionic contrast medium" compared in NEPHRIC. Absent from the bid summary is any mention of another LOCM, i.e. Isovue, or any statements that seek to extrapolate NEPHRIC's findings to another LOCM. Essentially, the TF members were left to weigh the value of NEPHRIC and the other studies cited with respect to Visipaque.

Visipaque safety claims are the most salient feature of the NFC portion of the summary and likely account for most of the large disparity in GEH's and Bracco's NFC scores.[204] Mr. Sweeney, although not a member of the TF, admitted that the TF members likely read GEH's bid summary to mean that Visipaque has superior safety to other CM and less pain than "traditional LOCM" which would include Isovue.[205] GEH's GPO expert admitted that Bracco's NFC score certainly could have

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[204] P4137:633-633.1,634; Sweeney T 122-87.

[205] Sweeney T 147-52; P4137:633-633.1; see also 36 T 220-229, 37 T 4-18. Mr. Sweeney testified that safety was at least as important as any other factor to the TF and that GEH's bid summary contains superior safety claims only for Visipaque. Sweeney T 184-7.

been lowered by GEH's Visipaque safety claims. Bracco alleges that the clinical information in the summary was so misleading that Mr. Sweeney thought that the NEPHRIC and COURT studies might have been against Isovue.[206] However, Mr. Sweeney was not on the Novation TF, and was only responsible for the financial aspect of the bidding process, without any sophisticated knowledge of the clinical nature of GEH's bid. In fact, Mr. Sweeney conceded that he has limited knowledge of the clinical studies that evaluated the efficacy and safety of Visipaque. (Sweeney T 175-77). Accordingly, his lack of knowledge regarding scientific names of drugs (i.e. iohexol vs. iodixanol) that were represented in various studies is not probative of what was understood by the decision-makers - - the TF members - - because they had the underlying studies and were able to come to their own decisions regarding the efficacy of the products. Furthermore, the Court does not find this to be a substantial factor in the bid, because the vast majority of the material in the summary was not false or misleading and consisted of appropriate advertising materials which touted the NEPHRIC study results in an acceptable way, (See 37 T 6, 21; 36 T 220-229). The Court finds that any inaccurate information in the summary, limited as it was, did not have a material impact on the TF, particularly when combined with the TF members' satisfaction with GEH's products and GEH's longstanding relationship with Novation.

viii. The Consorta Contract

In 1999, Consorta entered into a five-year, sole-source contract with Bracco for supply of x-ray and MRI CM.[207] Consorta put the contract out for bid in 2003 and received bids from at least

[206] Sweeney T 177,161,166,175-6; 37 T 9-10, 14-16; 16 T 70-71; 1 T 104-105, 18 T 173.

[207] D2098 at Consorta 321; D204 at A143080; 12 T 94:5-12.

Bracco, GEH, Berlex, and Tyco/Mallinckrodt.[208] In January 2004, Consorta awarded separate sole-source contracts to GEH for X-ray and MR agents (Bracco is seeking only damages for loss of the X-ray contract). (P702). The X-ray contract awarded to GEH by Consorta was a three-year sole source contract.[209] Consorta's Award Rationale states: "The imaging subcommittee agreed that the clinical acceptability of radiographic [x-ray] agents [(e.g. - Isovue, Visipaque, and Omnipaque)] would not be an issue,"[210] nonetheless, it also states that "Bracco's ProHance™ [(Bracco's paramagnetic agent)] . . . had not garnered high compliance . . . and that determining clinical acceptance of the paramagnetic agents was a critical step in the decision making process." The Consorta Award Rationale later states that GEH "was the only company that could provide clinically acceptable products, with formidable market positions, for both our radiographic and paramagnetic needs [and furthermore, that GEH] "is the only manufacturer of Isosmolar Contrast Media (Visipaque™)." [211]

GEH avers that the reasons for the award were: (1) GEH is the only manufacturer of Iso-osmolar CM; (2) GEH's more competitive prices for Omnipaque and Visipaque; (2) low clinical acceptance of Bracco's MRI product, ProHance; and (3) Consorta's belief that Bracco acted unethically during the bidding process.[212] Also, the Consorta members' satisfaction with GEH's

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[208] D2098 at Consorta 321; D204 at A143080; 12 T 217:8-12.

[209] D2098; D204.

[210] D2098 at Consorta 0322; D204 at A143081.

[211] D2098 at Consorta 0322; D204 at A143081; see also D411-T at B266403; D123 at B168211; 12 T 220:1-3, 228:15-233:3; 19 T 115:19-116:6.

[212] D1761.

products, based in part on their own clinical trials, contributed to their decision to contract with GEH.[213]

Bracco asserts that, despite all the abovementioned factors, that GEH's false advertising campaign was a material factor in the Consorta Award. The Court disagrees, but will begin its analysis by looking at internal GEH dialogue and the dialogue between Consorta and GEH. Mr. Jay Rapp, National Accounts Director at GEH, told Mr. Smith, his supervisor, that "[w]e need to drive as much Visipaque business within Consorta accounts as possible between now and the RFP process."[214] Mr. Smith agreed "Visipaque will be key to our success" and said the "POA should [include] specific elements for increasing Visipaque sales."[215] Mr. Rapp told Consorta's Dan Ingram, Manager of Imaging Contracts, that Visipaque "must be part of the [financial] comparison," and further stated in an internal GEH email that Dan Ingram "understands this, but we need to make this clear at the [July 2003] presentation as well as individual meetings ... and explai[n] the cost of

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[213] D212 at Consorta 003 (Staff commented that several shareholders conducted clinical trials with [GEH]'s products. The Imaging Sub-Committee reported that all of the trials went extremely well and in some cases facilities did not want to switch back to the Bracco products after trialing [GEH]'s.").; P702 at A250540; D204 at A143081; 19 T 117:21-118:22; D212 at CONSORTA 002, 003; Smith T 130:14-131:24.

[214] P781:704; 12 T 101, 113-114. See also P788:215, 654, 625, 789:275-6, 793, 787; 9 T 131-132; 18 T 174-175; P630, 451.

[215] P709; 12 T 105-108. The POA instructed representatives to "[p]enetrate accounts with Visipaque . . . by utilizing the key clinical differentiating advantages" and "ALWAYS lead with Visipaque and the NEPHRIC data and uniquely position Visipaque for the high risk and at risk patients." P386:353,358,359; 12 T 122-125. See also P676 ("all Consorta key influencers [most] clearly understand the consequences of using Omnipaque and Omniscan vs not. . . . Effectively communicating the Visipaque story is vital to us winning this contract."), 616 ("[o]ur pricing strategy on Visipaque will be a crucial part of the Consorta decision"), 621, 783, 786:201. GEH carefully tracked representatives' compliance with the Consorta POA. P623, 683, 684, 656, 611, 626, 707, 792, 765; 703, 643.

not using Visipaque." (P629; 12 T 111-112; P4226, 608). GEH's July 2003 presentation devoted nine slides to Visipaque's alleged benefits (versus three Omnipaque slides). (P782:890-901; 12 T 138-148). Bracco points to evidence that Consorta "asked about Isovue with respect to Omnipaque/LOCM as positioned in NEPHRIC" and that GEH responded: "it is Isosmolar versus low-osmolar that was studied [in NEPHRIC], not necessarily Visipaque versus Omnipaque." (P682; 2 T 153-157).

GEH's statements emphasize the possible extension of the NEPHRIC head-to-head study to all LOCM, and at the same time deflect negative reaction away from Omnipaque. The above statement is ambiguous at best, but is not necessarily false, because the NEPHRIC study and article devotes part of its analysis to extending the conclusion from the two CM studied, Visipaque versus Omnipaque, to Visipaque versus other LOCM. Furthermore, NEPHRIC hedged its conclusion to say that Visipaque may perform better than a LOCM. The Court does not find that NEPHRIC was unreliable for this latter conclusion, but does find that GEH must disclose that the two CM used in the study were Visipaque and Omnipaque, and that GEH may not extend NEPHRIC's results to a claim that Visipaque performs better than any LOCM other than Omnipaque. Here, Consorta was clearly aware that NEPHRIC compared Omnipaque and Visipaque. However, Bracco contends that GEH took its advertising a step further.

One example of the alleged false advertising in the GEH presentation was a NEPHRIC slide claiming "high risk patients 11X less likely to develop CIN with an isosmolar CM, iodixanol, than with a low-osmolar CM." (P782:A251897). However that same slide also presents a chart showing iodixanol (Visipaque) versus iohexol (Omnipaque). (Id.) While this slide appears to obscure the name brands of the products tested, it still presents the two CM that were tested in the study. Thus,

the slide was not false, but it may have been misleading. Bracco contends that the aftermath of this presentation was that a Consorta "inside person" reported that GEH "made a good showing" and "Visipaque is something that has to be considered." (P680; 12 T 158-160). But, this does not tell the Court whether it was the slides that made an impact.

As far as cost, Consorta told GEH it was "very concerned with Visipaque because of the impact increased use will have on Expense Budgets," and Ron Smith concluded that "it will be imperative ... to effectively communicate ... a clinical reason ... to justify Visipaque use in high risk patients" and "it is essential that we clearly show the consequences on Visipaque pricing in a win and lose scenario." (P612, 666; 12 T 174-178). GEH's RFP response emphasized the alleged clinical superiority of Visipaque; for example, GEH stated: "the safety profile of Isosmolar Visipaque [] has propelled its growth in recent years" and "[c]ontrast with higher osmolalities could affect patients with at-risk conditions...." (D945:425-6,430; 12 T 179-180). Nonetheless, these statements are nothing new to the medical community, and certainly have not been disproven. The Court finds that inserting the word *"could"* merely re-states the conclusion of the NEPHRIC study, and does not contain additional spin. Notwithstanding, as set forth herein, more precision will be required of GEH"s ads in the future as limited by this Opinion. In short, an implication that NEPHRIC's conclusions can be applied to any LOCM other than Omnipaque will not be permitted based on NEPHRIC alone. In addition, any comparative advertisement based upon a study must be consistent in its reference to the names of the drugs tested; for instance, if GEH were to advertise the comparative results of NEPHRIC, its reference to the drugs must be "Visipaque v. Ominipaque" **or** "iodoxianol v. iohexol."

Consorta's January 2004 press release stated that GEH's products were "preferable due to Amersham's range of product that includes . . . the only iso-osmolar agent Visipaque available in the United States." (P702:540; 12 T 197-199). Consorta's internal announcement shows that its "Award Decision" was based in part on increasing use (and costs) of Visipaque. (P715:851-2; 12 T 201-203; P163:110, 146). Mr. Smith recognized how crucial Visipaque Leverage was to GEH's win, stating that Consorta "had to consider what would happen to prices if Consorta went away from us [i.e.,] with Visipaque ... so we just can't assume that our offer was $6 million better than Bracco's offer. It wasn't." (P1469).

Bracco asserts that the most direct evidence of Visipaque Leverage is a memorandum produced by Consorta itself. In that document, Consorta compared the prices of a dual source award, Bracco (X-ray) / Berlex (MR), to a sole source award to GEH. (D212:004 (col. 2 and 3)).[216] The "three year spend" in the GEH column is slightly (0.4%) lower than the Bracco/Berlex column, but only because a Visipaque line item is included under Bracco's heading. Bracco argues that if that Visipaque line item is replaced with Isovue, Bracco would have won the contract by a comfortable margin.[217] This evidence, however, does not establish that GEH's false advertising was a material

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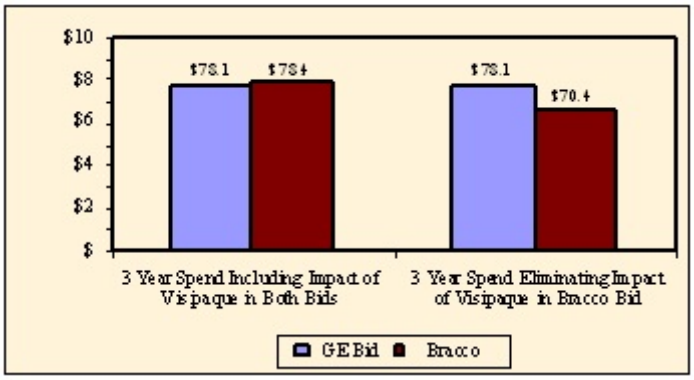
[216] Column 2 uses Bracco's clarified pricing for Isovue, in which rebates are taken off of list price, rather than net. Both parties agreed that Bracco had always previously calculated its rebates off of list price. 12 T 103; P4223; P788:215; 21 T 183-184. There is no dispute that Consorta *invited* Bracco and all other bidders to clarify their bids. 21 T 178-181; D1358, 206 (Strong letter stating "other suppliers were indeed given the opportunity to respond"), 212:3 ("Bracco was directed to [clarify its bid] in writing by the next day"). But see D212:003 (Consorta meeting minutes recommending that "in the future" clarifications should not be allowed). Moreover, GEH made a series of post-bid rebate clarifications of its own (12 T 188-197; P4219, 4221, 4220, 4227) and learned Bracco's exact Consorta pricing. 12 T 97-103; P4223, 781:704.

[217] 18 T 174-175,183-185; 19 T 74-75; P869, 451, 2758, 176, 177, 179, 4219, 4221, 4227; D434.

factor in the award; all it means is that Consorta viewed Visipaque as "a must have" product. Since Consorta could have come to this conclusion by reading the NEPHRIC article, and agreeing with its conclusions, it does not mean that the limited false or misleading ads GEH disseminated to Consorta were a substantial factor, particularly in light of other facts, as set forth below.



1. GEH's prices were more competitive than Bracco's prices

The primary reason Consorta switched suppliers for its 2004 contract was pricing.[218] Consorta determined it would save about $16 million over three years by accepting GEH's bid over Bracco's bid, notwithstanding Bracco's efforts to convince Consorta that the actual cost of contracting with GEH would be higher than contracting with Bracco.[219] Bracco decided not to lower its price for Isovue, despite being aware before submitting its bid that Consorta wanted lower prices.[220] Even Bracco, in hindsight, recognized that it should have offered Consorta a lower price

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[218] D212 at CONSORTA004; accord D204 at A143081; 21 T 215:6-216:8; D121; D118 at B285077; D202 at B074946; D1357; 37 T 188:7-189:1, 192:10-193:20; 12 T 213:8-214:21; Smith T 184:23-185:7; D203.

[219] 21 T 216:9-15; D 117 at B426316-18.

[220] 21 T 129:11-130:22, 140:2-19, 142:4-24, 148:18-24, 153:22-154:1, 158:2-159:16, 162:17-169:9; D2388AA at B284951 ("[S]ome concern was noted [by Consorta] regarding Bracco's decision to hold firm on further price reductions."); D2388CC at B285048; D674; D65; D1711 at

during the contract extension negotiations.[221] Mr. Malackowski, Bracco's damages expert, admitted that GEH's bid was less than Bracco's initial bid due to the low Omnipaque price, even after accounting for so-called "Visipaque leverage."[222] However, the second bid by Bracco was competitive. One of the key issues was pricing in the event that Consorta obtained a dual source contract with GEH and Bracco. Under those conditions, GEH would have charged a bigger premium for Visipaque which effectively made the GEH bid better. This shows that Consorta took into account that Visipaque was the only isosmolar CM on the market. In light of these findings, this Court disagrees with Bracco's assertion that GEH's false advertising as to Visipaque renal superiority over LOCM had a material effect on the bid process. Bracco has not demonstrated that the few false ads shown by GEH to Consorta were a material factor in its favorable view of Visipaque.

2. Bracco's ProHance product was not well accepted

Another asserted reason for Consorta's award was the low compliance with the MR portion of its contract when Bracco was the incumbent.[223] Consorta's members had clinical concerns about

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B289570; D2388-V at B286615 ("Consorta is looking for Bracco to demonstrate a compelling value proposition with price as a central point to the discussions . . . ."); D64 at B091484.

[221] D1761 (Winning the Consorta contract "came down to a clinical issue and a price issue and [Bracco was] in the weaker position on both fronts."); D1766 ("If we had approached Consorta with even a portion of the level of concession [on price] we are now willing to make to Novation, I assure you we would still have that contract!").

[222] 19 T 133:6-135:23.

[223] D2098 at Consorta 321-22; D204 at A143080-81; D64 at B091484; 19 T 117:8-20; 21 T 144:2-8, 154:2-155:24, 158:2-160:3, 215:6-216:8; 22 T 14:18-18:7; Smith T 157:19-158:21; D65 at B430469.

ProHance, including its inducement of vomiting.[224] Not surprisingly, Consorta officials were highly receptive and impressed with GEH products, so much so that some, based on their own clinical trials, wanted to continue using GEH products. Although a dual source bid would have alleviated concerns about the ProHance product and was an option that would have had competitive pricing had it not been for the Visipaque premium, Consorta's award rationale appears to be based primarily on GEH's ability to provide clinically acceptable products across all spectrums as contrasted with Bracco. Thus, the Court finds that GEH's limited false advertising was not a material factor, while Bracco's failing ProHance product was a material factor in Consorta's award rationale.

3. Consorta believed Bracco acted unethically in bidding

After the suppliers submitted bids to Consorta, Bracco learned through "competitive intelligence" that GEH had submitted a much lower bid.[225] Bracco then restructured its bid so that it was similar to GEH's and submitted a revised bid.[226] Consorta believed that it would be unethical for it to consider the revised bid.[227] Indeed, Bracco's internal documents also attribute the loss of

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[224] D2098 at Consorta 322 ("Bracco's ProHance…had not garnered high compliance (due to reported patient reactions) forcing many Consorta facilities to purchase competitive product off-contract."); D204 at A143081; see also 12 T 214:22-216:4; 28 T 10:4-12; 37 T 188:7-189:1, 193:21-196:3; Smith T 157:19-158:21; D1761; D63; D203; D131 at B275869.

[225] D66; D2422 at B502245; 21 T 169:23-172:22, 180:19-181:1.

[226] D212 at Consorta 002; D118 at B285077 ("We believe the restructured proposal makes our pricing consistent with Amersham's."); D2388DD at B289915**;** D119; 21 T 181:14-197:5; 22 T 20:17-26:9; D434; D937 at B433103; D938 at Consorta 013; D2422 at B502244-45; Smith T 141:9-24, 143:18-20, 145:19-146:17, 168:14-16, 168:21-169:22; D1358 at B087234.

[227] D212 at Consorta 002 ("The Sub-Committee discussed [Bracco's enhanced bid] and stated that we should not accept this offer as this would be unethical."), Consorta 003; D435; D437; D1358 at B087235; D206 at Consorta 0180 (President and CEO of Consorta finding Bracco's conduct "to raise further troubling ethical issues"); 37 T 188:14-189:1, 199:24-200:7; 21 T

the Consorta contract to a variety of other factors, unrelated to alleged false advertising, including Bracco's lack of understanding of Consorta's contracting process and a lack of "depth and breath [sic] of relationships" between Bracco and Consorta.[228] Consorta's subjective view of Bracco's actions in the bid process, as opposed to GEH's advertising, sounded the death knell for Bracco's bid.

ix. GEH's Allegedly False Visipaque Claims And Leverage were not a Material or Substantial Factor in the Award of the Kaiser Contract

In August 2003, GEH signed a sole-source agreement with the Kaiser IDN, even though Kaiser had joined the Broadlane GPO which had a sole-source contract with Bracco. Bracco avers that GEH's allegedly false claims about Visipaque were a material factor in GEH's contract win at Kaiser and that it is shown by GEH's post-award analysis that GEH won the contract by demonstrating to Kaiser that its "contrast media spend budget would increase" as a result of "increased Visipaque penetration" and a "[p]rice increase from 45% to 20% off list for Visipaque if they switched to Bracco and Broadlane."[229] However, the Court fails to see how this links the alleged false advertising with the Kaiser bid. Offering a more competitive price and offering other products at a discount for putting other GEH products on contract is an acceptable business practice. In addition, GEH had held a sole source agreement with Kaiser for the supply of x-ray CM since

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198:19-207:21, 210:16-215:5; 22 T 4:20-6:11.

[228] D1761; D123 at B168207; 21 T 210:22-212:22; see also D1711.

[229] P1490 ("Visipaque's growing penetration within Kaiser ... drove this process"), P1491, 1492, 717:877; 18 T 185-186; 19 T 75-76.

1993 and had enjoyed a favorable relationship with Kaiser.[230] In addition, during negotiations for an extension, GEH lowered its price on Omnipaque.[231] There is no evidence that advertising played any role in the renewal.

II. GEH'S Counterclaim

GEH alleges that Bracco has disseminated ads in violation of 43(a) of the Lanham Act and New Jersey State Law. During the course of trial GEH stipulated to dropping all claims for damages in its counterclaim, leaving only a request for injunctive relief. (36 T 4-8). In Bracco's Revised Findings of Fact (¶ 96) it stipulated that the Bracco ads and promotions identified by GEH (except D2013) in connection with its counterclaim are no longer in use. Bracco contends that due to this stipulation any injunctive relief against Bracco would have no effect on GEH, Bracco or the market.

A. Bracco's Comparison of Results from Kay and NEPHRIC

GEH contends that Bracco advertisements (e.g. D3, 31, 2014, 2015) promote Isovue as less renally toxic than Visipaque and/or Omnipaque. In order to make that claim, Bracco relies on the results of the Kay study and represents in these advertisements that NEPHRIC and Kay were similar studies.[232] GEH argues that the two studies were not similar because: (1) NEPHRIC patients were at greater risk for renal injury than patients in Kay; (2) NEPHIC patients received a greater iodine

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[230] P1490 at A291512, 513.

[231] 19 T 130:25-131:4.

[232] Specifically, D2014 states that the groups tested in both studies were "very similar with regard to demographic and other baseline characteristics. . .as well as iodine does administrated," and D 2015 referred to the NEPHRIC and Kay studies as "similar." D 2014; D 2015. Likewise, in D 3, a letter signed by Dr. Spinazzi and sent to over 30,000 doctors, asserts that Isovue is safer than Omnipaque, specifically comparing the results of NEPHRIC to the Kay study. D 3.

dosage than the Kay patients; and (3) Kay did not even report the iodine concentration of Isovue used. In support of its contention that D2014 and 2015 disseminated false messages, GEH proffered Dr. Harold Feldman, who testified that in his opinion, the studies were not comparable. (E.g., 21 T 139:12-159:13; 32 T 73:23-75:5). The Court finds that Bracco's advertisements that compare the results of Kay and NEPHRIC advance comparisons that are unreliable given the distinct differences between Kay and NEPHRIC, specifically that the patients in NEPHRIC had a substantially higher risk of renal injury than those patients in the Kay study. Indeed, any claim of Isovue superiority over Visipaque and/or Omnipaque based on comparative results of the Kay and NEPHRIC studies strays too far from the actual results.

III. Daubert Motions

Necessarily, the Court must dispose of remaining evidentiary issues in connection with the admission of expert testimony. At trial, numerous experts for both sides testified on a broad swath of subjects ranging from the reliability of clinical studies using contrast media to testimony on the impact and dissemination of the parties' marketing materials. These experts provide the lynchpin to the parties' claims. Furthermore, expert testimony is critical in establishing damages and proving liability under certain prongs of the Lanham Act's false advertising regime.

A. Standard

Federal Rule of Evidence 702 requires that only reliable testimony, offered with a sufficient factual basis, be admitted. It was amended in response to the Supreme Court's decision in Daubert v. Merrell Dow Pharms., Inc., which established a "gatekeeping role for the judge," whereby the court must determine the admissibility of expert testimony. 509 U.S. 579, 597 (1993). Kumho Tire v. Carmichael explained that the Court's gatekeeper function applies not only to cases involving

"scientific" knowledge but also in cases involving "technical" and "other specialized" knowledge. 526 U.S. 137, 141 (1999).

Together, Daubert and Rule 702 impose three requirements for admissibility of expert testimony: "qualification, reliability, and fit." Calhoun v. Yamaha Motor Corp., 350 F.3d 316, 321 (3d Cir. 2003). First, the witness must have specialized expertise appropriate to his testimony. Feit v. Great-West Life and Annuity Ins. Co., 460 F. Supp. 2d 632, 636 (D.N.J. 2006). Second, the testimony must be reliable, which excludes opinions based on subjective belief or speculation; the opinion instead must "reliably flow from the facts known to the expert and the methodology used." Id. at 637. Third, the testimony must be relevant to issues in the case and assist the trier of fact. Id. at 636.

B. Motion to Preclude the Expert Reports and Testimony of John Russell

Mr. John Russell, Bracco's pharmaceutical marketing expert, has 33 years of experience in sales, sales management, sales operations, product management, new product launches, reimbursement, pricing strategy, contracting strategy, market research, and business planning concerning pharmaceuticals. Mr. Russell authored four expert reports and testified about pharmaceutical sales and marketing. Bracco asserts that his testimony is intended to provide a full and detailed understanding of the manner in which pharmaceutical companies traditionally sell and market their products as well as his understanding of GEH marketing and sales practices. His opinions were informed by analyzing GEH internal documents, deposition transcripts, review of other expert reports and discussions with people in the specific field of selling CM.

1. Mr. Russell's Opinions on Whether Alleged Implicit "Messages" Contained in GEH Advertisements and Internal Documents are False are Excluded.

Mr. Russell testified that GEH documents, including advertisements and sales call notes, contained implicit messages. He based his conclusions on other expert reports provided to him. (17 T 12:25-13:10). During trial, the Court stated that Mr. Russell, who is not a physician or scientist, and has no experience with contrast media, may provide testimony based on the assumption that Defendants' disseminated messages were false, but that he is not qualified to make an independent determination of their falsity. (17 T 12:25-13:10, 106:6-107:3-5). Mr Russell also testified to customers' supposed expectations of pharmaceutical advertising. (17 T 49:9-15). However, Mr. Russell did not conduct or rely on any official customer survey for his opinions (17 T 34:14-18), and relied primarily on his own belief of what customers would understand and expect. (18 T 10:7-24, 11:20-14:3, 14:14-18:18, 21:2-22:2, 22:8-23:12).

The Second Circuit has discussed the critical role of customer surveys in the context of establishing a claim of false advertising under the Lanham Act.

> Generally, before a court can determine the truth or falsity of an advertisement's message, it must first determine what message was actually conveyed to the viewing audience. Consumer surveys supply such information. Once the meaning to the target audience has been determined, the court, as the finder of fact, must then judge whether the evidence establishes that they were likely to be misled.

Johnson & Johnson Merck Consumer Pharms. Co. v. Smithkline Beecham Corp., 960 F.2d 294, 298 (2d Cir. 1992) (citations and quotations omitted). Furthermore, the Second Circuit went on to state that:

> Absent such a threshold showing, an implied falsehood claim must fail. This follows from the obvious fact that the injuries redressed in false advertising cases are the result of public deception. Thus, where the plaintiff cannot demonstrate that a statistically significant part of the commercial audience holds the false belief allegedly communicated by the challenged advertisement, the plaintiff cannot establish that it suffered any injury as a result of the advertisement's message.

> Without injury there can be no claim, regardless of commercial context, prior advertising history, or audience sophistication.

Id. In addition, the Third Circuit has concluded that, in the context of direct marketing to consumers, an expert's "personal opinion is not the legal standard by which courts must determine whether customers were misled" and that absent evidence such as customer surveys, no court can conclude that consumers were mislead. See Johnson & Johnson-Merck Consumer Pharms. Co. v. Rhone Poulenc Rorer Pharms Co., 19 F.3d 125, 136 (3d Cir. 1994).

Here, Mr. Russell's opinion as to falsity of messages is not only unsupported, but is also irrelevant to the issue of customers' understanding and reaction to the advertisements. Therefore, the Court finds that Mr. Russell's net opinion or personal belief about alleged implicit messages or customers' expectations is legally irrelevant because he is not a member of the relevant purchasing group, did not rely on a survey of this group, and is unqualified to opine on the issue of how physicians would evaluate and act upon scientifically oriented ads or promotions for x-ray contrast media. Consequently, Bracco cannot rely on Mr. Russell's testimony as a substitute for its failure to conduct an adequate survey.

2. Mr. Russell's Opinion on Intent, the Actions of Sales Representatives, Causation, and Sales Call Notes are Unreliable.

a. Mr. Russell Cannot Opine on GEH's State of Mind

Mr. Russell purported to divine what GEH was "trying" to do with its marketing strategy and what it believed was right or wrong. (See, e.g., 17 T 65:6-17, 66:19-22, 81:14-16). However, as the Court stated during trial, experts cannot opine on intent. (17 T 4:19-7:18); see AstraZeneca LP v. TAP Pharm. Prods., Inc., 444 F. Supp. 2d 278, 293 (D. Del. 2006) (precluding expert opinion of what party recognized, felt, concluded, or was concerned about and recognizing that expert witnesses

are not "permitted to testify . . . regarding [the defendant's] intent, motive, or state of mind, or evidence by which such state of mind may be inferred."); In re Rezulin Prods. Liability Litig., 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) (concluding that "[i]nferences about the intent or motive of parties or others lie outside the bounds of expert testimony"). Accordingly, the Court strikes Mr. Russell's testimony to the extent that it opines on the intent or state of mind of others.

b. Mr. Russell's Speculation About the Actions of GEH Sales Representatives is Unreliable

Mr. Russell speculated that GEH sales representatives posted protocols for Visipaque usage; that conclusion is unreliable and in conflict with the factual record. (17 T 101:13-14). During the course of trial, the Court quoted Crowley v. Chait, which concluded that no expert or "any other witness will be permitted to simply summarize the facts and the depositions of others. Such testimony comes 'dangerously close to usurping the [factfinder's] function' and 'implicates Rule 403 as a needless presentation of cumulative evidence and a waste of time.'" 322 F. Supp. 2d 530, 553-54 (D.N.J. 2006) (quoting United States v. Dukagjini, 326 F.3d 45, 54 (2d Cir. 2003)). GEH witnesses uniformly and credibly testified that Visipaque protocols were not posted, (6 T 75:1-7; 15 T 191:9-22; 16 T 151:17-152:1), and accordingly, the Court finds that it is not Mr. Russell's function as an expert to judge the credibility of those witnesses, or to supplant the factual record with speculative testimony.

c. Mr. Russell's Testimony Regarding Causation is Unreliable

GEH argues that Mr. Russell's opinions about causation, (See, e.g., 17 T 115:12-18, 116:1-5, 116:12-21, 117:1-4), are speculative and unreliable because he has no experience with contrast agent purchasing decisions and did not fully consider the factual record. It is true that Mr. Russell never

negotiated a contract to sell contrast agents to a GPO or hospital (17 T 31:8-11), was never on a committee evaluating contrast agents (17 T 31:12-15), never made purchasing decisions at a hospital or GPO (17 T 31:16-18), and has not worked on any GPO contract since 1992. (17 T 31:19-21). Furthermore, the Court finds that Mr. Russell did not undertake a systematic or scientific analysis of all factors to determine the specific effect of any particular piece of advertising, (i.e., he did not separate out the effect of any particular piece of advertising, marketplace effects or influences other than alleged false advertising, including true advertising). (17 T 34:3-38:12).

For example, with regard to Consorta and Novation, he failed to consider the economics of the bids (17 T 145:12-20, 148:5-11, 150:18-20, 166:12-25), and in the case of Consorta, did not consider Bracco and Consorta documents showing that Consorta was displeased with Bracco's conduct during the bidding process and with its MRI agent ProHance (17 T 145:3-20; D 2098 at Consorta 0322; D 204 at A143081; D 212 at Consorta 002). Mr. Russell also failed to talk to Bracco executives about the Consorta contract (17 T 145:21-146:24), and did not consider GEH's long-time incumbency at Novation, despite opining that Bracco's incumbency at Consorta was a reason that it would have kept the contract. (17 T 168:14-170:4).

GEH argues that Mr. Russell's opinions about customer purchasing decisions are connected to the facts of the case only by his own ipse dixit and thus, are unreliable. See Calhoun, 350 F.3d at 321(where the court excluded testimony that offered opinions on specific matters without a reliable foundation); Ortiz v. Yale Materials Handling Corp., No. 03-3657, 2005 U.S. Dist. LEXIS 18424, at *15 (D.N.J. Aug. 24, 2005) (holding that "[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered" and thus exclude the expert's testimony). Nonetheless, an expert need not take into account every possible factor in rendering an

opinion. See MicroStrategy Inc. v. Business Objects, S.A., 429 F.3d 1344, 1355 (Fed. Cir. 2005) ("While an expert need not consider every possible factor to render a 'reliable' opinion, the expert still must consider enough factors to make his or her opinion sufficiently reliable in the eyes of the court."); Callahan v. A.E.V., Inc., 182 F.3d 237, 257 (3d. Cir. 1999) (where the court rejected defendant's argument that an expert report was inadequate because it failed to rule out every possible alternative cause for plaintiff's loss); Yarchak v. Trek Bicycle Corp., 208 F. Supp. 2d 470, 498 (D.N.J. 2002) ("a medical expert's causation conclusion should not be excluded merely because he or she failed to rule out every possible alternative cause of a plaintiff's illness.") (citation omitted).

In this case, while Mr. Russell did undertake an analysis of internal GEH documents which were produced during the discovery period before trial, but see Section 3, p. 84, infra, he did not take into account numerous, or indeed, most relevant factors as to causation. Thus, his opinion is not reliable.

d. Mr. Russell's Testimony Regarding the Percentages of Alleged "clinical differentiation messages" in GEH's Sales Call Notes is Unreliable

Mr. Russell opined as to the percentage of GEH sales call notes he believed were "clinical differentiation messages" or "on-message," and the percentage of sales representatives who had delivered the same (see, e.g., 17 T 102:15-21, 107:8-16). However, on cross examination, Mr. Russell admitted that the "on-message" compilation he relied on had been done by Bracco's counsel (18 T 26:2-7, 29:7-16), and he could not explain why a number of notes had been included at all (18 T 36:17-37:1, 44:3-45:7, 46:5-18). When pressed, Mr. Russell testified that mere mention of the word NEPHRIC justified inclusion in his "on message" tallies (18 T 33:22-34:4). In fact, even

when the word NEPHRIC was not mentioned in the call note, Mr. Russell speculated that it had been promoted during the sales call (18 T 34:21-35:25). He also included notes in which he could not determine if the statement at issue was made by the sales rep or the doctor (18 T 38:25-41:19). Because of these numerous shortcomings, Mr. Russell's "on-message" analysis is unreliable and is hereby excluded.

3. To the Extent that Mr. Russell's Testimony Was Nothing More Than an Attempted Summary of, and Spin On, Internal GEH Documents it is Excluded

The Court finds Mr. Russell's testimony helpful to the extent that he provides information as to how a marketing department operates, however to the extent that Mr. Russell's testimony reflected no more than his summary of, and spin on, internal GEH documents (see, e.g., 17 T 51:8-11, 69:24-70:3, 80:22-81:17, 119:6-22), the Court finds that such testimony is unhelpful to the Court as the trier of fact and excludes such testimony from the record. This is because the documents speak for themselves and do not require expert testimony to discern what they mean.

C. Motion to Exclude Mr. Malackowski's Testimony

Mr. James E. Malackowski was proffered by Bracco to opine about causation and damages. As stated in his expert report, he provides opinions on valuation, asset and risk management and is an expert in the field of intellectual capital equity management. In the past, he has served as an expert in numerous cases relating to intellectual property economics and the determination of economic damages in disputes concerning intellectual property infringement, breach of contract, and false and misleading advertising. Indeed, he is eminently qualified in these areas. In this action, he has submitted four expert reports and he testified at trial.

1. Mr. Malackowski's Testimony With Respect to the Issue of Causation is Limited to his Assumption that Causation Existed

Mr. Malackowski assumed that causation existed. (19 T 106:16-21, 107:17-21, 131:8-20). Mr. Malackowski has no expertise as to why doctors prescribe certain drugs or why GPOs award certain contracts. (19 T 104:17-106:4). Thus, he was qualified only as an expert with respect to the quantification of damages, not the issue of causation. (19 T 86:25-91:11). Nonetheless, while Mr. Malackowski is only qualified as an expert on damages, in his damages assessment the Court permitted him to use GEH internal documentation such as GEH's annual marketing plans, which in some instances attribute sales growth to specific events, such as the publication and dissemination of the NEPHRIC data. This testimony is intricately tied to damages and is not excluded. (See 18 T 141-142).

2. Malackowski's Damages Calculations Fail to Distinguish Between the Marketplace Effects of Tortious and Non-Tortious Conduct

Defendants argue that Mr. Malackowski failed to account for the marketplace effects of activities other than GEH's alleged false advertising, thus making his damages testimony in connection with Vispaque sales unreliable. To support their contention, Defendants rely on a series of cases that have excluded expert testimony when it failed to take into account the effect of non-tortious activity in its calculations. See IQ Prods. Co. v. Pennzoil Prods. Co., 305 F.3d 368, 376-77 (5th Cir. 2002) (affirming exclusion of expert report where expert considered combined effect of two allegedly tortious acts, but did not consider them independently, and one was determined to be non-actionable); Concord Boat Corp. v. Brunswick Corp., 207 F.3d 1039, 1055-57 (8th Cir. 2000) (holding that expert testimony should not be admitted when it fails to separate lawful from unlawful conduct); See also MicroStrategy Inc., 429 F.3d at1353-56; Children's Broad. Corp. v. Walt Disney

Co., 245 F.3d 1008, 1018-19 (8th Cir. 2001); Blue Dane Simmental Corp. v. Am. Simmental Ass'n, 178 F.3d 1035, 1039-41 (8th Cir. 1999); El Aguila Food Prods. Inc. v. Gruma Corp., 301 F. Supp. 2d 612, 624-26 (S.D. Tex. 2003), aff'd, 131 Fed. Appx. 450 (5th Cir. 2005).

Nonetheless, Plaintiff argues that it is not necessary for a damages expert to account for all possible sources of the injury to establish causation. The Third Circuit has held that "[c]ourts that reason that the injury could have taken place without . . . advertising are misstating the relevant tort liability principles, which ask whether the advertising did in fact contribute materially to the injury." Frog, Switch & Mfg. Co., Inc. v. Travelers Ins. Co., 193 F.3d 742, 751 n.8 (3d Cir. 1999) (citation omitted). However, this does not address Defendants' argument that Mr. Malackowski's testimony is unreliable; it merely confirms the standard which is needed to establish causation. Since this Court has already ruled that Mr. Malackowski's testimony in connection with causation is not admissible because he assumed causion, Plaintiff's recitation of the causation standard is not germane.

Here, Mr. Malackowski assumed that the publication of NEPHRIC itself (as well as other articles favorable to Visipaque) constitutes false advertising, and included the effect of its publication in his damages analysis without differentiating it from GEH's other alleged false advertising. (19 T 129:4-9, 129:23-130:5). But, since the Court finds that NEPHRIC itself does not constitute false advertising, see infra p. 127-28, then GEH's alleged false advertising must be differentiated from the effect of NEPHRIC on Visipaque sales. To counter this argument, Bracco directs the Court to Mr. Malackowski's testimony in which he states that it would not change the results of his account specific approach to calculating damages if the Court finds that NEPHRIC does not constitute false advertising. (19 T 130:2-14). Similarly, Mr. Malackowski testified that if

the NEPHRIC article were true that it would be accounted for within the sales trend approach in market growth rates because sales trends only go higher as the market grows. (Id.)

The record demonstrates that Mr. Malackowski did not attempt to break down the injury to Bracco by particular ads or brochures. (19 T 109:24-110:8, 165:4-7, 176:4-12). The Court recognizes this as an attempt to avoid having to apportion any amount of damage (under any of his multiple theories) to any particular advertisement or type of advertisement. Thus, if any of GEH's promotional efforts were proper, which this Court has found to be the case, then Mr. Malackowski has failed to account for the market effects of these non-tortious efforts. Mr. Malackowski's failure to account for the effects of non-tortious activity is fatal to the validity of his calculations since the Court finds the NEPHRIC article itself to not be a form of false advertising. Indeed, his "analysis" blames false advertising for: (1) 100% of the alleged drop-off in Bracco's sales occurring after NEPHRIC; (2) 100% of Amersham's Visipaque sales; and (3) 100% of Visipaque's higher price (as compared to other contrast agents). (18 T 93:6-12; 19 T 107:17-108:17, 114:18-25, 143:6-14, 164:15-165:3, 176:4-7).

3. Malackowski's Damages Calculations as to Bracco's Expenditures on Corrective Advertising

Finally, Bracco proffers Mr. Malackowski's testimony to support its request for damages relating to corrective advertising and clinical trials done in response to NEPHRIC and GEH's Visipaque advertising campaign. Although the Court excludes Mr. Malackowski's testimony with regard to disgorgement and lost profit damages based upon an assumption of causation, which the Court finds is not supported, his opinions with regard to recovery of corrective advertising, past and future, are not subject to the same attack. Different from his disgorgement and lost profits analysis,

the same causation analysis does not apply. In that light, the Court finds Mr. Malackowski's opinion as to past and future corrective advertising costs reliable.

D. Motion to Exclude Mr. Pines' Testimony

Mr. Wayne Pines was proffered by Bracco as an expert on FDA practices and regulations. His experience includes monitoring FDA regulation of marketing materials and advertisements. He was retained to provide testimony relating to the FDA and GEH's advertising and promotion of its x-ray contrast agents, Visipaque and Omnipaque.

1. Mr. Pines' Testimony Relating to FDA Guidelines and GEH Compliance with the Same Is Legally Irrelevant

GEH urges the Court to exclude Mr. Pines' testimony that the FDA standard for superiority claims requires "substantial evidence," which he acknowledged was defined by the FDA as two or more adequate and well controlled studies, each directly comparing the same two products. (14 T 216:10-217:2, 218:12-220:3; 15 T 43:1-7). GEH asserts that under the Lanham Act standard, neither FDA statements about the lack of "substantial evidence," nor Mr. Pines' spin on the same are relevant. Indeed, the Third Circuit has declined "to blur the distinctions between the FTC and [the] Lanham Act [because it] would require [courts] to ignore the separate jurisprudence that has evolved under each Act, and the sound reasoning that underlies it." Sandoz Pharms. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 229 (3d Cir. 1990). In Sandoz, the court further held that "it is not sufficient for a Lanham Act plaintiff to show *only* that the defendant's advertising claims of its own drug's effectiveness are inadequately substantiated under FDA guidelines; the plaintiff must also show that the claims are literally false or misleading to the public." Id. (emphasis added). For instance, a defendant could advertise the results of one adequate well-conducted study showing

superiority of its product (clearly not a Lanham Act violation), yet lack "substantial evidence" under the FDA standard. Nonetheless, Defendants' reliance on Sandoz is misplaced because here FDA guidelines and statements regarding Visipaque are not the only evidence to support Plaintiff's Lanham Act claim.

Thus, while the Court declines to substitute the FDA standard for those under the Lanham Act, the Court finds the FDA's response to be probative and not irrelevant. Courts have recognized that an FDA finding about the strength and veracity of a study's conclusions about a pharmaceutical product to be persuasive evidence and helpful in determining if those conclusions were also false under the standard promulgated in the Lanham Act. See Zeneca Inc. v. Eli Lilly and Co., No. 99-1452, 1999 WL 509471, at *18 (S.D.N.Y. 1999) (in a Lanham action, the court found the FDA's conclusions to be persuasive when the FDA reviewed all the data from a trial, met with the study investigators and scientists and determined that based on its review that the study does not and cannot prove that the drug reduces the risk of breast cancer); SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharmaceuticals, Co., No. 95-7011, 1996 WL 280810, at *13 (S.D.N.Y. May 24, 1996) (court declined to substitute its opinion for that of the FDA where manufacturers had to submit studies to the FDA proving safety and effectiveness of over-the-counter medication in order to obtain approval for package labeling); see also American Home Prods. v. Procter & Gamble, 871 F. Supp. 739, 754 (D.N.J.1994) (expert's conclusion concerning efficacy of analgesic is "bolstered by the FDA's formal findings" concerning the product). Similarly, this Court finds that Mr. Pines' testimony on this issue is properly admitted.

E. Motion to Exclude Dr. Rappeport's Testimony

Dr. Michael Rappeport, a Bracco expert, is a marketing and survey research expert with 35 years of experience. He has testified over 200 times in the areas of statistics, statistical analysis, marketing, and public opinion in disputes such as trademark infringement, libel, damages, and reapportionment. During trial, he testified regarding a survey that he conducted to determine physicians' perceptions of GEH's website advertising. Dr. Rappeport's survey was carried out by DIR, a California based company. A total of 80 radiologists and 30 interventional cardiologists were interviewed and the survey referenced re-created web pages from the Visipaque portion of GEH's website. The Court made a finding at trial that Dr. Rappeport was qualified to provide testimony in the field of designing, conducting, and analyzing surveys. (22 T 36-37).

1. Dr. Rappeport's Survey is Unreliable

Defendants attacked the reliability of Dr. Rappeport's trial testimony and underlying survey in their original Daubert motion on various grounds, asserting and highlighting: (1) uncertainties surrounding the material actually tested in his survey and Bracco's failure to preserve it for review; (2) that his testimony is not helpful to the trier of fact; (3) problems with the definition of the survey population and the selection of respondents; (4) problems with the reporting and analysis of his data; and (5) problems with the design and administration of the survey. The Court notes at the outset that Dr. Rappeport's survey is replete with problems that undermine the survey's reliability. (D.I. 375). To state a few, the survey: (1) failed to identify the correct survey population by not asking survey respondents whether they were in any way responsible for the purchase of contrast media; (2) failed to use an adequate control mechanism to determine whether the respondents may have had preexisting or predominant views prior to viewing the advertisements that may have affected their decision; and (3) failed to correctly characterize certain statements made to the survey participants;

for example, one statement was prefaced with the statement "the makers of Visipaque state," when the statement was actually a direct quote from the NEPHRIC study, a peer reviewed article in the New England Journal of Medicine. These factors all lead the Court to conclude that Dr. Rappeport's survey is inherently unreliable and that even if it were admitted that it would be given little or no weight.

Initially, the Court strikes Dr. Rappeport's survey as it pertains to the 30 interventional cardiologists interviewed. This is based on the fact that the web pages re-created by DIR for the survey administered to the 30 interventional cardiologists were never produced at trial, nor were their contents testified to by a witness with personal knowledge. Dr. Rappeport testified that he never saw the web pages that were re-created and used for the survey and neither counsel nor Dr. Rappeport were able to produce the original email from Dr. Rappeport which allegedly contained the web pages used in the survey. (22 T 65-66). Because displaying the web pages in the same manner as the website is critical to obtaining accurate and reliable survey results, and this information is lacking, the Court finds this portion of the survey unreliable.

The Court also finds that Dr. Rappeport's survey with regard to the 80 radiologists is also fatally flawed and hence unreliable. First, the web page that was presented to the survey respondents did not contain a clickable link, as the actual GEH website did, to view the abstract of the NEPHRIC study. (22 T 74). Second, at trial, Dr. Rappeport gave inconsistent testimony about the interviewer's instructions. First, he testified that they were instructed to write down anything material that the respondents asked or said, but then he testified that they were instructed to write down everything that they heard. (22 T 75). This discrepancy in what the interviewers were instructed can skew the results, especially in conjunction with the fact that the respondents were not able to click on a link

that would have allowed them to view the abstract of the NEPHRIC study. Third, the survey asked the participants whether they thought: "the makers of Visipaque are claiming reduced nephropathy compared to all brands of low-osmolar non-ionic contrast mediums, some but not all brands of low-osmolar non-ionic contrast mediums or just one specific brand of low-osmolar non-ionic contrast mediums?" According to Dr. Rappeport, this is a closed question which was designed to cover all possibilities. However, as shown in the survey, one respondent did not answer the question, demonstrating that the questions did not account for the participants that might have had no opinion on the matter. (22 T 80-81). Fourth, Dr. Rappeport attributed a quote from the NEPHRIC article, which was on the GEH website, to the makers of Visipaque. (22 T 82-83). While the website certainly contained the NEPHRIC quote, it may introduce a bias to attribute the statement incorrectly to the makers of Visipaque. Consequently, this also skews the survey's results.

Fifth, the survey failed to identify the correct sample population; none of the survey questions established whether the participants were in any way responsible for the purchase of contrast media. Even without asking this question, many survey respondents independently stated that they were not involved in making the purchasing decision, and that their use of the product was mainly because the hospital uses that brand product, not because the respondent had any impact or influence on the purchasing decision. This is a critical flaw in the design of the survey, which makes it significantly less useful for determining whether consumers who were making the actual purchasing decision were deceived, a critical question in this case. During trial, Dr. Rappeport stated that in his opinion, all doctors influenced the purchasing decision for CM because it would be unethical for them to administer a product which they did not feel was the best product. (22 T 99-103). He came to this opinion by conducting a so-called pre-test where he contacted physicians and asked them questions

so that he could become knowledgeable about the subject matter for the survey. (Id. at 103). The physicians that he contacted were not part of the actual survey. (Id.) In addition, Dr. Rappeport gave inconsistent testimony about how many physicians he interviewed for this pre-test. First he said 6, then he said 10, then he said it may be about 9 or so. (Id. at 103-105). He also stated that these physicians were friends, and friends of friends, all of whom were in the New Jersey and Pennsylvania area, not nationwide. (Id.) Furthermore, Dr. Rappeport testified that at least one of them was not even a radiologist or an interventional cardiologist. (Id. at 105). Dr. Rappeport then went on to state that all of the physicians in the pre-test stated that they personally make the decision as to what contrast agent they administer to patients, however yet again, the question of whether they were involved in the purchasing decision was never asked. (Id. at 108-109). The Court finds the quantum of Dr. Rappeport's testimony to be unclear and his methods for conducting the survey not consistent with usual accepted practices; for these reasons the Court strikes the testimony and survey results of Dr. Rappeport as unreliable.

Case law from this district as well as others supports the contention that Dr. Rappeport's survey needed control mechanisms to be reliable. For example, one court in the District of New Jersey opined: "[i]t is clear that in a false advertising action survey results must be filtered via an adequate control mechanism to screen out those participants who took away no message from the advertisement as well as to account for those consumers who may have brought to the survey certain publicly held preconceptions regarding the product." American Home Products Corp., 871 F. Supp. at 761-62; see also Merck Consumer Pharmaceuticals Co., 960 F.2d at 298 (concluding that where a portion of the survey population may have held extrinsic beliefs prior to viewing an advertisement, a control mechanism "would likely be indispensable").

Furthermore, the Court notes that in addition to other courts excluding expert testimony on similar grounds, another court specifically excluded one of Dr. Rappeport's surveys because it did not use a proper control group. In Procter & Gamble Pharmaceuticals, Inc. v. Hoffmann - LaRoche Inc., the court reasoned that the fact that the physician survey lacked any control was a marked departure from generally accepted market research practices, rejecting Dr. Rappeport's contention that "a control group is unnecessary for sophisticated respondents like doctors, who are unlikely to 'guess.'" No. 06-0034, 2006 WL 2588002, at *25 (S.D.N.Y. Sept. 6, 2006). Here, on cross examination, counsel confronted Dr. Rappeport with the fact that his lack of a control group has been rejected by other courts and Dr. Rappeport's testimony reflected that although he did not think a control group is necessary for doctors, not all courts agree with him. (22 T 126-128). Additionally, he said that the main downside of using a control group is money, something that the Court finds to be disingenuous for this particular case, especially given the apparent staggering amount of legal fees and costs related to expert testimony.[233] (Id.) Accordingly, the Court finds no basis for Dr. Rappeport to fail to use control group in this case, and that his survey is unreliable for lack of a control mechanism, similar to the courts' analysis in American Home Products Corp., Johnson & Johnson, Merck Consumer Pharmaceuticals Co. and Procter & Gamble Pharmaceuticals, Inc.

In addition to the grounds asserted in Defendants' initial Daubert brief for exclusion of the testimony of Dr. Rappeport, Defendants assert in their post trial supplemental Daubert brief that Dr. Rappeport's trial testimony revealed that his survey did not include the required number of participants to meet his own reliability standards. Specifically, Dr. Rappeport surveyed 80

[233]For example, testimony revealed that Mr. Malackowski's expert fee was $500,000. In addition, on any given day of trial, multiple attorneys, technical personnel, and experts were present in the courtroom.

radiologists and 30 interventional cardiologists. (22 T 73:10-12). However, the interventional cardiologists were shown a re-created website that Dr. Rappeport never saw, was never produced or shown to GEH, and was not introduced at trial. (22 T 60:23-61:22, 64:16-65:13). The Court disallowed reliance on the results of the interventional cardiologists subject to Bracco's production of the re-created website, which it never did produce. (22 T 68:14-72:11, 74:1-75:24, 147:7-150:13). Absent the interventional cardiologists, per Dr. Rappeport's own admission, the survey was too small to meet prospectively defined reliability requirements. (22 T 110:21-111:10). Thus, the Court excludes Dr. Rappeport's testimony in connection with his survey in its entirety.

F. Motion to Exclude Dr. Schmittlein's and Dr. Stewart's Testimony as Unsupported by Facts or Analysis

Dr. David Carl Schmittlein and Dr. Marion Stewart are two experts, proffered by GEH, to rebut the expert testimony of Mr. Russell and Mr. Malackowski. Dr. Schmittlein is a Professor of Marketing at the Wharton School of Business at the University of Pennsylvania. His expertise is specifically within the field of measuring consumer perceptions, preferences, and behaviors, and the link between these measures and marketing programs. Dr. Stewart is an economist and senior vice president of National Economic Research Associates (hereinafter "NERA").

Bracco argues that the testimony from GEH's Dr. Schmittlein (36 T) and Dr. Stewart (37 T-38 T), regarding the cause of Bracco's harm, is unreliable and lacks fit. Bracco incorporates its motions in limine (D.I. 344 and 384) and identifies additional arguments for exclusion as follows: (1) both experts asserted that there were possible causative "factors" that Bracco's experts should have considered; (2) both experts failed to conduct any factual investigation into Bracco's harm, the contrast agent market, or GEH's practices to inform their testimony; (3) both experts failed to use

any appropriate scientific methodology, such as interviewing knowledgeable people, reviewing GEH's internal analyses or applying a survey or other experimental tool, to support their testimony; and (4) both experts failed to use any information except that which was spoon fed to them from GEH's counsel.

As to Bracco's first argument, it asserts that neither expert fit the factors to this case, such as by determining that the factors applied to the relevant market or that there were additional material factors entitled to weight, (36 T 43-52, 54, 58-83; 37 T 174-177) and that both GEH experts explicitly testified that they did not know enough to weigh these factors and determine any value to be accorded to them. (Id.) To support its assertion of lack of fit, Bracco looks to both Mr. Malackowski and Mr. Russell's extensive investigations of GEH's internal documents and examinations of the market as an example.[234] Bracco contends that Mr. Malackowski and Mr. Russell actually did look for and examine the facts in issue for the factors the GEH experts asserted may apply and found no evidence for them, thus concluding that GEH's alleged false NEPHRIC advertising caused the harm that is the focus of its damages calculation. (See, e.g., 17 T 40-53, 64-132; 18 T 132-186; 19 T 59-76; see also Malackowski Expert Reports; Russell Expert Reports).

The Court finds that Dr. Schmittlein's and Dr. Stewart's "fit" to the facts of this case is too loose for the Court to allow admission of their testimony as to the external factors that they assert should have been taken into account in Mr. Malackowski and Mr. Russell's methodology of

[234]Specifically, Bracco contends that Mr. Malackowski and Mr. Russell made a thorough review of the market that included all such factors through their review of thousands of documents (e.g., GEH market research, sales calls, instructions to the sales force, marketing plans and analyses, reports from the field, and other market analysis), interviews with or from participants (e.g., users of the products, sales representatives, depositions of GEH personnel), independent research, review of the technical literature themselves and via the reports of other technical experts.

determining damages. Bracco argues that both experts failed to conduct any factual investigation into Bracco's harm, the contrast agent market, or GEH's practices to inform their testimony, (36 T 54, 58-83; 38 T 35-102; Ex. E and F), further asserting that such testimony is unreliable and inadmissible under Daubert. See, e.g., Crowley, 322 F. Supp. 2d at 541-542; see also Ortiz, 2005 U.S. Dist. LEXIS 18424, at *21-23 (excluded for no independent investigation of accuracy of accident reports); JMJ Enters. v. Via Veneto Italian Ice, Inc., No. 97-0652, 1998 WL 175888, at *6-8 (E.D. Pa. Apr. 15, 1998) (excluded for no independent investigation of damage numbers provided by client); Chemipal Ltd. v. Slim-Fast Nutritional Foods Int'l, 350 F. Supp. 2d 583, 589 (D. Del. 2004) (excluded for no investigation of the methodology used in the third party marketing projections); JRL Enters. v. Procorp Assocs., No. 01-2893, 2003 U.S. Dist. LEXIS 9397, at *14, 22-23 (E.D. La. June 3, 2003) (excluded where "conducted no independent investigation of these numbers," but instead relied on the client ' s numbers); TK-7 Corp. v. Estate of Barbouti, 993 F.2d 722, 732 (10th Cir. 1993) (excluded where relied on figures calculated by another without independent investigation).

The testimony provided by Dr. Schmittlein and Dr. Stewart was a composite of criticisms and conclusions based upon the methodology used by Bracco's experts, Mr. Malackowski and Mr. Russell. In the Court's view, these opinions would have benefitted from independent market analysis to properly critique Bracco's experts. Moreover, their testimony may not be used to determine qualitatively the actual causes of Bracco's failure to obtain the GPO contracts at issue.

Third, Bracco argues that both experts failed to use any appropriate scientific methodology, such as interviewing knowledgeable people, reviewing GEH's internal analyses or applying a survey or other experimental tool, to support their testimony (36 T 54, 58-83; 38 T 35-102). Bracco asserts

that this does not comport with Rule 702. This Court agrees. Fourth, Bracco argues that both experts failed to use any information except that which was given to them by GEH's counsel (36 T 25-31, 38-41, 79; 38 T 35-102; Exhs. E and F). Bracco relies on a Third Circuit case which held that a medical expert's testimony must be excluded when it was based on medical history summaries that were generated through interviews conducted by nonprofessionals aligned with counsel. In re TMILitig., 193 F.3d 613, 698 (3d Cir. 1999), amended by, 199 F.3d 158 (3d Cir. 2000). However, In re TMILitig. is not analogous to the present case because Dr. Schmittlein's and Dr. Stewart's analyses were not based on summaries generated by GEH's counsel, but were based on analyses of the methodology of Mr. Malackowski and Mr. Russell's expert reports. Nonetheless, both Dr. Schmittlein's and Dr. Stewart's testimony and related exhibits are excluded for the other reasons set forth herein.

G. Motion to Exclude the Testimony of Dr. Schmid Based on Lack of Fit and Validity

Dr. Christopher Schmid is an expert in statistical analysis, proffered by GEH, who provided testimony during the course of trial regarding general statistical principles, general principles of performing clinical studies used to evaluate efficacy and safety of drugs, and evaluation and statistical analysis of the results from clinical studies. Bracco argues that portions of Dr. Schmid's testimony (37 T) are inadmissible for failure to fit them to the facts, failing to provide a basis for the testimony at trial or in reports, and having no valid scientific basis. For the reasons below, the Court finds that Dr. Schmid's generalized testimony was not properly fit to the statistical analysis of studies used in this case, and that his opinions of hypothetical abstract statistical analysis cannot be used to attack particular ads and studies, which were not addressed directly in his testimony. This prevented

Bracco from being able to cross examine the witness about specific studies and the specific circumstances of each one, which Defendants seek to undermine through generalized testimony.

First, Bracco asserts that Dr. Schmid's testimony on general statistics (37 T 84-104) and his comparison of results from single arms of different clinical trials (37 T 137-139) was never related to the facts of this case and thus there is no fit with the "particular disputed factual issues in the case. " Milanowicz v. Raymond Corp., 148 F. Supp. 2d 525, 530-31 (D.N.J. 2001) (quoting In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741-43 (3d Cir. 1994)). In particular, in response to Bracco's objections on these grounds (37 T 100) and its attempt to cross-examine Dr. Schmid and relate his testimony to the facts (37 T 139-150), GEH itself objected, stopped Bracco's objections and cross-examination, and admitted that its strategy was to not relate Dr. Schmid's testimony to any particular study or ad offered into evidence by Bracco, but merely to testify as to the unreliability of comparing single arms of different clinical trials. (37 T 100-101, 139-150). Bracco asserts that such testimony is inadmissible as a matter of law. See Fed. R. Evid. 702 (e.g., expert "may testify . . . if . . . (3) the witness has applied the principles and methods reliably to the facts in the case); Paoli, 35 F.3d at 742-43. Daubert explains that "[fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." Daubert, 509 U.S. at 591. Bracco argues that GEH and Dr. Schmid never related these opinions and conclusions to any facts during trial, and that they should not be permitted to provide such a linkage solely through attorney argument in post-trial briefing. The Court agrees.

Second, Bracco argues that Dr. Schmid' s very limited testimony concerning the NEPHRIC study (37 T 104-132), is inadmissible because he gave no basis for it in either his reports or at trial. GEH claimed that the testimony was necessitated by testimony from Bracco's witness, Dr. Solomon,

five months earlier, when he testified that the 25% secondary endpoint of the NEPHRIC study led to an opposite conclusion to the study's primary end point as opposed to an inconsistent conclusion to the study's primary end point. (37 T 123-126). GEH was permitted to ask a question specifically tailored to that new testimony regarding an "opposite conclusion," which was not precisely the language used in Dr. Soloman's expert report. (e.g., 37 T 126-132). Bracco argues that Dr. Schmid did not review the NEPHRIC statistical plan, statistical report, study data or the study report and he did not talk to the NEPHRIC investigators or read their testimony, thus asserting that Dr. Schmid's testimony regarding this issue lacks a proper foundation. However, the Court will allow his testimony regarding this very limited issue because he is an expert qualified in the field of biostatistics, his testimony distinguishing the difference between what an "inconsistent" secondary end point as opposed to an "opposite" secondary end point means does not require an additional factual foundation than that to which he had access.

Third, Bracco argues that Dr. Schmid's testimony on confidence intervals must be excluded as unreliable because it was in disagreement with the vast weight of scientific knowledge. Rule 702 (e.g., expert "may testify . . . if . . . (2) the testimony is the product of reliable principles and methods"). Bracco argues that in connection with confidence intervals, Dr. Schmid admitted that even though he was giving hypothetical examples, they were incorrect (37 T 94). He testified using examples showing that confidence intervals for certain values were symmetric around a value, when such symmetry is impossible (37 T 91-96). The Court agrees that his testimony was unreliable and will strike this testimony.

Lastly, Bracco argues that in connection with p-values, despite having no support in his reports, Dr. Schmid several times testified that the 0.05 p-value test for statistical significance was

not grounded in solid science (37 T 98 ("It ' s just tradition . . .”); 37 T 140 ("done for traditional purposes")). Bracco contends that those statements are incorrect as a general matter and that it is also incorrect in the specific clinical studies in issue in this case, including the Chalmers study, the NEPHRIC study, the VALOR study, and in every other instance of import in this case, where the expert clinicians, editors and statisticians explicitly chose, on a prospective basis, the 0.05 p-value as appropriate for determining whether any difference was likely due to chance or not. Bracco states that Dr. Schmid's post hoc analysis violates the rules and underlying rationale for performing scientific analysis in a prospective, unbiased manner and that such testimony, (i.e., 37 T 132, 134-135), based on flawed methodology and flawed assumptions should be excluded. See Total Containment, Inc. v. Dayco Prods., Inc., No. 97-6013, 2001 WL 1167506, at *4-5 (E.D. Pa. Sept. 6, 2001); JMJ Enters. v. Via Veneto Italian Ice, Inc., No. 97-0625, 1998 WL 175888, at *8-10 (E.D. Pa. April 15, 1998); In re Med Diversified, Inc. v. Addus Healthcare, Inc., 334 B.R. 99, 100 (E.D.N.Y. 2005); Lippe v. Bait-two Corp., 288 B.R. 678, 701 (S.D.N.Y. 2005), aff d, 99 Fed. Appx. 274 (2d Cir. 2004); Club Car, Inc. v. Club Car (Quebec) Imp., Inc., 362 F.3d 775, 780 (11th Cir. 2004), (striking of testimony based on flawed methodology that was unaccepted in the accounting community). The Court agrees – Dr. Schmid is a qualified bio-statistician – but his testimony regarding the use of the p-value is not properly based upon science and is not reliable. The basis for his opinions and conclusions on this issue will therefore be excluded by the Court.

H. Motion to Exclude Dr. Ericksen's Testimony as Inadmissible

Dr. Eugene P. Ericksen, proffered by GEH, is an expert in statistical analysis and a special consultant with NERA Economic Consulting. He gave testimony during the course of trial and designed a survey to determine the impact of marketing pieces shown and distributed by Bracco to

physicians. Bracco contends that Dr. Ericksen's testimony (35 T) and related GEH survey (D326), ostensibly relating to a Bracco brochure and letter, were flawed in several respects, such that they render his opinions and testimony unreliable, lacking fit and otherwise of no help to the Court. Bracco incorporates its related motion in limine (D.I. 393) and identifies the alleged flaws as follows: (1) the survey used three cropped and out of context snippets taken from a Bracco brochure (D2014) and a letter sent to doctors (D3); (2) the survey used the three snippets orally over the telephone despite the uncontested fact that the documents (and the snippets) were meant to be read (not heard) and handled and thus the survey did not in any way simulate marketplace conditions, as again Dr. Ericksen admitted, (35 T 211-212, 215, 217-218); (3) certain of the survey questions misrepresented the snippet used (e.g., parentheses in question 16 were not communicated thereby changing its meaning (35 T 159-161, 181-182, 228-232); and (4) counsel for GEH chose the snippets that were tested and helped design the survey, demonstrating its lack of probative value and Dr. Ericksen's failure to provide objective and reliable analysis and testimony (35 T 222).

As to Bracco's first contention, the survey withheld from the respondents large amounts of other essential visual, contextual and informational portions from the two documents that directly relate to the survey questions, as Dr. Ericksen admitted. (35 T 225-237; D2014 (e.g., withheld graphs and portions showing differences in patient populations); D3 (e.g., withheld Kay paper, six bullet points and the descriptions of the studies and patients)). The Court finds that the survey results thus have no probative value as to whether there was false or misleading advertising or the effect of any advertising on a customer, and as such, the Ericksen testimony is excluded.[235]

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[235] E.g., 35 T 211-212, 222-225 (D3465, p134); Scotts Co. v. United Indus. Corp., 315 F.3d 264, 280 (4th Cir. 2002); Sears, Roebuck & Co. v. Menard, Inc., No. 01-9843, 2003 U.S. Dist. LEXIS 951, at *5, 10 (N.D. Ill. Jan. 22, 2003).

As to Bracco's second contention, the problem of presenting the material orally as opposed to in writing does present a problem, but only because all three snippets are difficult to understand when heard orally (35 T 157-160) and more appropriate internet-based or other methods were available but not used (35 T 212-214, 217-218). Thus, Bracco argues that the survey has no probative value.[236] The Court agrees.

Bracco's third contention is that certain of the survey questions misrepresented the snippet used (e.g., parentheses in question 16 were not communicated thereby changing its meaning (35 T 159-161, 181-182, 228-232); questions 14, 14al, 14b, 14c asked about a study "comparison" divorced from the snippet and thus asked for the respondents' own comparison (35 T 178-179, 180, 245-246)) and suggested answers (e.g., initial questions focused respondents on high risk, CIN and different information about the Kay and NEPHRIC articles and included suggestive preambles (35 T 154-156, 237-239, 243-247); prefaces to questions 13 and 15 provided non-objective opinions (D326)), rendering the survey unreliable, inconclusive and lacking fit to the facts in issue — i.e., whether ads were false or misleading. Again, the Court concurs.

Fourth, Bracco contends that Dr. Ericksen's lack of objectivity was also confirmed by how he interpreted his results (e.g., without justification he leapt from responses to questions about "any input into the decisions made about which contrast agents to use" to the conclusion that "the physicians were responsible for the selection" and the physicians were the persons who "made these decisions" (35 T 150-154, 215-216)) and the wording of critical questions that were asked (e.g., a

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[236]Bracco relies on the following cites. See also Simon Prop. Group L.P. v. mySimon, Inc., 104 F. Supp. 2d 1033, 1041 (S.D. Ind. 2000); Trouble v. Wet Seal, Inc., 179 F. Supp. 2d 291, 308 (S.D.N.Y. 2001).

snippet said "similar populations" but the respondents' answer choices were limited to "same," "different," or "did not know," in contravention of proper survey practice (35 T 165-167, 169-170, 196); he illogically asked doctors who had no input in decisions for patients how the snippets would change their input in decisions for patients (35 T 202)).[237]

Lastly, Bracco avers that Dr. Ericksen admitted that his results cannot be extrapolated to other snippets or documents, such as any ads or promotions themselves (35 T 237-239). Thus Bracco argues that GEH's survey and Dr. Ericksen's testimony, including his conclusions, should be excluded from evidence as unreliable, lacking fit and any probative value. The Court agrees for all of the aforementioned reasons and excludes Dr. Ericksen's testimony.

IV. Conclusions of Law

A. Bracco's Case in Chief

1. False Advertising Claims Under the Lanham Act or New Jersey State Law

This case is based upon a claim for false advertising, and thus, the Court's analysis must begin with Section 43(a)(1)(B) of the Lanham Act which provides in relevant part:

> (a)(1) Any person who, on or in connection with any goods or services ... uses in commerce any word, term, name, symbol, or device, or any combination thereof, or

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[237]The survey was also confounded by not excluding the respondents' memory from more than two years earlier, of the discontinued brochure and letter, in initial questions (D326; 35 T 154-156), and in the face of the respondents receiving other similar documents from Bracco and GEH at the same time and after, that they would have confused their memories of these with documents (e.g., other similar brochures, the earlier March Spinazzi letter to doctors on the same subject matter (Dl), the GEH Vitti letters to doctors on the same subject matter (P2163)), creating a flawed memory test with a high risk of testing both faulty memories and perceptions, thus rendering the survey unreliable and inadmissible hearsay. See, e.g., Pittsburgh Press Club v. United States, 579 F.2d 751 (3d Cir. 1978) (inadmissible hearsay in polling context); United States v. Southern Indiana Gas & Elec. Co., 258 F. Supp. 2d 884, 893-94 (S.D. Ind. 2003) (survey with a hearsay risk of faulty memory unreliable).

> any . . . false or misleading description of fact, or false or misleading representation of fact, which-
>
> . . . (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her . . . goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1)(B). A Lanham Act plaintiff must prove that: "(1) that the defendant has made false or misleading statements as to his own product [or another's]; (2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; (3) that the deception is material in that it is likely to influence purchasing decisions; (4) that the advertised goods traveled in interstate commerce; and (5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc." Warner-Lambert Co. v. BreathAsure, Inc., 204 F.3d 87, 91-92 (3d Cir. 2000); Rhone-Poulenc, 19 F.3d at 129 (quoting U.S. Healthcare, Inc. v. Blue Cross of Greater Phila., 898 F.2d 914, 922-23 (3d Cir.1990)). "However, '[i]f a plaintiff proves a challenged claim is literally false, a court may grant relief without considering whether the buying public was misled.'" Warner-Lambert Co. 204 F.3d at 92; Johnson & Johnson-Merck, 19 F.3d at 129; see also Castrol, Inc. v. Pennzoil Co., 987 F.2d 939, 943 (3d Cir.1992).

Furthermore, unfair competition claims under New Jersey statutory and common law generally parallel those under §43(a) of the Lanham Act. Buying For The Home, LLC v. Humble Abode, LLC, 459 F. Supp. 2d 310, 317-318 (D.N.J. 2006); see J & J Snack Foods, Corp. v. Earthgrains Co., 220 F. Supp. 2d 358, 374 (D.N.J. 2002) ("[T]he elements for a claim for trademark infringement under the Lanham Act are the same as the elements for a claim of unfair competition under the Lanham Act and for claims of trademark infringement and unfair competition under New Jersey statutory and common law. . . ."); Harlem Wizards Entertainment Basketball, Inc. v. NBA

Properties, Inc., 952 F. Supp. 1084, 1091 (D.N.J. 1997) ("N.J.S.A. 56:4-1 is the statutory equivalent of Section 43(a)(1) of the Lanham Act").

2. Commercial Advertising Under the Lanham Act

The initial determination of whether a form of speech is actionable commercial speech is not always a simple question. The Court must begin its inquiry with the Supreme Court's jurisprudence in connection with the First Amendment and its application to different types of representations. As the Supreme Court stated in Bolger v. Youngs Drug Products Corp., 463 U.S. 60 (1983):

> [T]he First Amendment means that government has no power to restrict expression because of its message, its ideas, its subject matter, or its content. With respect to noncommercial speech, this Court has sustained content-based restrictions only in the most extraordinary circumstances. By contrast, regulation of commercial speech based on content is less problematic. In light of the greater potential for deception or confusion in the context of certain advertising messages, content-based restrictions on commercial speech may be permissible.

Bolger, 463 U.S. at 65 (citations and quotations omitted). The Supreme Court has also held that where the main purpose of a work is for noncommercial speech purposes but also contains a commercial speech component, thus leaving the commercial and noncommercial speech "inextricably intertwined, [to the point where the court] cannot parcel out the speech, applying one test to one phrase and another test to another phrase . . . [the court must] apply our test for fully-protected expression." Riley v. National Federation of the Blind, 487 U.S. 781, 795-96 (1988).

In City of Cincinnati v. Discovery Network, Inc., 507 U.S. 410 (1993), the Supreme Court again inquired into the distinction between commercial and noncommercial speech. There, the Court

> recognized the difficulty of drawing bright lines that will clearly cabin commercial speech in a distinct category. While the Court noted that it has often described the core notion of commercial speech as speech which does no more than propose a commercial transaction, it noted that it has also identified a somewhat larger category of commercial speech - that is, *expression related solely to the economic interests of*

> *the speaker and its audience*. Neither definition may prove particularly helpful in a particular case . . . [thus,] a broader and more nuanced inquiry may be required. [R]ather than simply applying bright-line rules, [courts must examine] restrictions on speech carefully to ensure that speech deserving of greater constitutional protection is not inadvertently suppressed.

Gordon & Breach Science Publishers v. Am. Inst. of Physics, 859 F. Supp. 1521, 537 (S.D.N.Y. 1994) (hereinafter "G&B") (summarizing Discovery Network, Inc., 507 U.S. at 410) (citations and quotations omitted) (emphasis added).

The seminal case on the application of the Lanham Act is G&B. In G&B, Judge Sand held that the Lanham Act prohibits only those false or misleading statements made in "commercial advertising [and] promotion." G&B, 859 F. Supp. at 1533; Seven-Up v. Coca-Cola, 86 F. 3d 1379, 1383 n.6, 1384 (5th Cir. 1996); Eli Lilly & Co. v. Roussel Corp., 23 F. Supp. 2d 460, 480 (D.N.J. 1998); Oxycal Labs. v. Jeffers, 909 F. Supp. 719, 722-23 (D. Ariz. 1995). The court then set forth a four part test for making a determination as to whether representations should be considered commercial or noncommercial speech, which has been followed in this district among others:

> The Lanham Act does not define "advertising" or "promotion." However, courts have held that commercial advertising or promotion consists of four elements: (1) commercial speech; (2) by a defendant in commercial competition with the plaintiff; (3) for the purpose of influencing customers to buy the defendant's goods or services; and (4) disseminated sufficiently to the relevant purchasing public to constitute "advertising" or "promotion" within the industry.

Eli Lilly & Co., 23 F. Supp. 2d at 480 (quoting G&B, 859 F. Supp. at 1536).

Accordingly, although the Lanham Act only applies to "commercial advertising and promotion," G&B and its progeny establish that the definition of commercial speech applies to more than just the typical type of advertising. Semco, Inc. v. Amcast, Inc., 52 F.3d 108, 112 (6th Cir.1995) (article written for trade magazine may be classified as commercial promotion); Bolger,

463 U.S. at 67-68 (mailing of informational pamphlets by nonprofit organization can be classified as commercial speech); G&B, 859 F. Supp. at 1534-36; Birthright v. Birthright, Inc., 827 F. Supp. 1114, 1138 (D.N.J.1993) (non-profit fundraising letters can be commercial advertising); National Artists Mgmt. Co. v. Weaving, 769 F. Supp. 1224, 1234-36 (S.D.N.Y.1991) (former employee's badmouthing of employer can fit into category of commercial advertising). In this case, there are various types of alleged commercial speech, each of which requires a separate and independent analysis as to whether it constitutes actionable "commercial advertising and promotion." At issue here are scientific articles in peer reviewed journals, internal GEH documents, oral statements made by GEH sales associates, CME materials, and a purported "Visipaque Protocol" allegedly distributed to potential physician customers.

a. Scientific Articles Published in Peer Reviewed Journals are not Commercial Speech

Defendants contend that published scientific articles, such as NEPHRIC and COURT, are protected by the First Amendment and are not actionable under the Lanham Act, regardless of the extent of their dissemination by a commercial entity; and furthermore, that published scientific research is protected even if it contains incorrect statements or erroneous conclusions. The Court finds that there is an abundance of case law to support the proposition that a scientific article is protected noncommercial speech despite the potential for erroneous content. See, e.g., Bd. of Trs. of Leland Stanford Junior Univ. v. Sullivan, 773 F. Supp. 472, 474 (D.D.C. 1991) ("It is equally settled, however, though less commonly the subject of litigation, that the First Amendment protects scientific expression and debate just as it protects political and artistic expression."); G&B, 859 F. Supp. at 1541-44; Oxycal, 909 F. Supp. at 723-26 (where the court held that a book containing false

statements about the content of a commercially produced vitamin was not actionable commercial speech because "the commercial elements of the speech [were] intertwined with the central message" which was noncommercial in nature); Neurotron, Inc. v. American Ass'n of Electrodiagnostic Med., 189 F. Supp. 2d 271, 275-77 (D. Md. 2001) (the court held that a nonprofit medical association's publication of an article which contained allegedly false statements about the defendant's electrodiagnostic medical devices was unlikely to constitute commercial speech because the authors of the article did not advocate for a commercial transaction; moreover the court reasoned that even if some language in the article was commercial in nature that it still would not necessarily constitute commercial speech).

Plaintiff relies on Semco for the proposition that "disseminating study results (e.g., journal articles) to promote products is commercial speech that has no constitutional protection to the extent it is false or misleading." (Pl.'s COL ¶ 4). In Semco, the court held that when the author of a published article is the president of the company that manufactures a product which is featured in the article, and the article contains favorably false information about the product, that the initial publication of the article is actionable under the Lanham Act against the manufacturing company. 52 F.3d at at 113-15.

However, as stated above, the Supreme Court's broadest definition for commercial speech is an "expression related solely to the economic interests of the speaker and its audience." Discovery Network, Inc., 507 U.S. at 422. In this case, none of the scientific articles in question meet that definition. The NEPHRIC article was published by the New England Journal of Medicine ("NEJM"), a widely renowned medical journal published for educational purposes and for the benefit of the medical field. This simply does not fit the definition of a representation that is solely related

to economic interests. In short, by going through the factors promulgated in G&B, and applying them to the NEPHRIC article: (1) the NEJM's main focus is for an educational purpose, which falls far short of the "solely commercial" requirement; (2) NEPHRIC was not published by a defendant in commercial competition. Despite the fact that Defendants sponsored the research for the article, they did not author it like the defendant in Semco. Dr. Aspelin, the author of NEPHRIC, was not paid by GEH for his work on the article; therefore Semco is inapposite and does not control for purposes of this case; (3) its publication was not commercial because it did not advocate that the reader purchase a particular product over another, even though it did come to specific scientific conclusions about which products, (Visipaque or Omnipaque) were better suited for certain medical purposes; and (4) although it was widely disseminated in the NEJM's distribution pool, it is a protected form of speech, distributed by an impartial educational journal in the field of medicine.

Furthermore, the Court finds that it would be inappropriate to "inquire into the validity of . . . scientific theories" which are not commercial speech and promulgated in scientific journals. Thus, it declines to do so today.[238] Oxycal, 909 F. Supp. at 724; see also Sanderson v. Culligan Int'l, 415 F.3d 620, 624 (7th Cir. 2005) (Lanham Act was not "designed to throw into federal courts all disputes about the efficacy of competing products . . . and scientific disputes must be resolved by scientific means," not federal courts). The Court recognizes the myriad of problems that might ensue from judicial forays into the field of scientific research and publication; as such, the Court adopts the analysis from the court in G&B:

[238]This conclusion is made in the context of non-commercial speech. It is not to say that the Court will refrain from inquiring into the reliability of such articles when they are used in a secondary dissemination in the form of commercial advertising.

> The conclusion we reach here is supported by a consideration of the chilling effect on speech in the academic and non-profit context that could be the result of allowing actions such as this to proceed. This case dangerously juxtaposes academic speech, the health of which depends crucially on "that robust exchange of ideas which discovers truth 'out of a multitude of tongues'," Keyishian v. Board of Regents, 385 U.S. 589, 603 (1967) - with commercial speech, regarding which the Court has said "[t]he government may ban forms of communication more likely to deceive the public than to inform it." Central Hudson Gas & Electric Corp. v. Public Service Comm'n, 447 U.S. 557, 563 (1980).

G&B, 859 F. Supp. at 1542. Thus, for the reasons stated above, the Court finds that the initial publication of the NEPHRIC article in the NEJM is not actionable commercial speech under the Lanham Act.

b. Secondary Dissemination of Scientific Articles and Their Findings do Constitute Commercial Speech

Plaintiff argues that even if the NEPHRIC article itself is not considered commercial speech, that the secondary dissemination of the article in Defendants' advertisements does constitute actionable commercial speech. To support this contention, Plaintiff relies on Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998), vacated in part on other grounds, 202 F.3d 331 (D.C. Cir. 2000), and G&B. Both cases celebrate the high level of protection given to scientific and academic research, however caution that secondary dissemination of that same information can constitute comme rcial speech in certain circumstances.

In Washington Legal Found., the court began its analysis by noting that: "It is beyond dispute that when considered outside of the context of manufacturer promotion of their drug products, CME seminars, peer-reviewed medical journal articles and commercially-available medical textbooks merit the highest degree of constitutional protection. Scientific and academic speech reside at the core of the First Amendment." Id. at 62; see, e.g., Keyishian, 385 U.S. at 603; Sullivan, 773 F. Supp.

at 474. Like in this case, there it was argued that "because this speech merits full protection when uttered by a scientist or academic, the level of constitutional scrutiny should not change merely because a corporation wishes to enhance the distribution of that message." Id.; cf. First National Bank of Boston v. Bellotti, 435 U.S. 765, 784 (1978) (holding that the expression of views on matters of public importance does not lose First Amendment protection merely because a corporation seeks to utter the speech); New York Times v. Sullivan, 376 U.S. 254, 266 (1964) (noting that statements do not lose constitutional protection because they are presented in the form of a paid advertisement).

Nonetheless, the court recognized that "[t]he peculiarities of the prescription drug industry make dissemination of scientific research results an especially important and prevalent marketing tool." Washington Legal Found., 13 F. Supp. 2d at 63. The court honed in on this concept to make its determination that secondary dissemination of fully protected scientific articles could be actionable commercial speech under the Lanham Act. The court reasoned that while there may be an abundance of resources in the form of scientific articles, CME seminars and the like, both opposing and favoring a certain product, it is likely that manufacturers will only seek to disseminate materials favorable to their product. Id. at 65.

> That fact, combined with the considerable financial resources available to pharmaceutical companies, means that findings concluding that a drug effectively treats a condition is more likely to reach a physician than studies reaching the opposite conclusion. Therefore, physicians could be led to believe that a certain drug is safe and effective because a manufacturer has found, and aggressively promoted, "the one" article that supports use of their drug, even if there exists considerable evidence to the contrary.

Id. This reasoning led the court in Washington Legal Found. to depart from the rigorous standard of review generally demanded by the First Amendment.

In G&B, the court also held that secondary distribution of scientific research articles could constitute actionable conduct under the Lanham Act if it is found to be false or misleading. G&B, 859 F. Supp. at 1544-45. In that case, plaintiffs, commercial publishers of scientific journals, brought an action against nonprofit scientific societies for false advertising under the Lanham Act for the publication of comparative surveys of scientific journals in which nonprofit journals were rated as superior. Id. at 1524-27. There the court distinguished between the defendant's initial publication of the article and its continued distribution of reprints at a librarians' conference, which was its target audience. The court reasoned:

> These are allegations of activities explicitly promotional in nature: distribution of survey results favoring defendants' products to an audience that represents the core consumers of those products. These activities clearly fall closer to Section 43(a)'s reach than does mere publication of the articles. They may properly be described as "commercial speech that a competitor employs for the express purpose of influencing consumers to buy [its] goods or services," or as "speech proposing a commercial transaction,"

Id. at 1544 (citation omitted). Thus, here again, the court concluded that secondary dissemination of a fully protected article can constitute a violation of the Lanham Act if false or misleading. Accordingly, because GEH's advertising campaign using the NEPHRIC article is clearly promotional in nature, similar to the advertising in G&B and Washington Legal Found, the Court finds that Defendants' secondary distribution of the NEPHRIC article does constitute a form of commercial speech.

i. Internal Company Documents That Were Never Publicly Disseminated in the United States Are Not Actionable

At the outset, the Court notes that internal documents such as marketing plans and medical bulletins do not constitute "commercial advertising or promotion" because they are not disseminated

to consumers, much less disseminated to a sufficient portion of the relevant purchasing public so as to constitute "advertising" or "promotion" within the industry, under the four element test promulgated by the court in G&B.

ii. Accused Oral Statements Allegedly Made by GEH Sales Representatives are Actionable Under the Lanham Act

GEH avers that the evidence presented at trial demonstrated that GEH sales call notes are, at best, "brief shorthand" notes that do not reflect verbatim statements made by sales representatives. (28 T 153:12-21; see also 18 T 38:25-41:19). GEH further argues that Bracco did not show that the accused GEH sales call notes reflect statements that were actually made, and cannot rely on them as grounds for its claim. Bracco accuses 87% of GEH's sales call entries of being false or misleading. GEH asserts that the percentage is grossly inflated. (GEH Findings of Fact (hereinafter "FOF") at ¶¶ 105-09). GEH asserts that Isovue is mentioned in only 284 call notes (0.09% of GEH's 314,468 notes), and that of those, at best, only 38 (or 0.012%) could even remotely be construed as including a superiority claim, with ambiguity still remaining as to whether the statements were made by the sales rep or by the customer. Accordingly, GEH asserts that Mr. Russell conducted an overly inclusive compilation of GEH's sales calls (with which the Court agrees) and that they were not enough in number to be sufficiently actionable. First, the Court must determine whether such sales call notes are indicative of the sales representatives' actual conduct; second, the Court will address whether there are sufficent sales call notes to be actionable.

Courts have consistently held that oral statements by a company's sales representative concerning a product constitute 'commercial advertising or promotion' under the Lanham Act." Zeneca Inc. v. Eli Lilly & Co., No. 99-1452,1999 WL 509471, at *31 (S.D.N.Y. July 19, 1999).

Bracco asserts, and the Court agrees, that the sales call notes are relevant evidence in establishing actionable commercial speech under the Lanham Act. In that regard, Bracco relies on a series of cases that use sales call notes as evidence of a campaign of false oral advertising. For example, in Zeneca Inc., the court found that "Eli Lilly representatives are trained and required to maintain written notes, prepared as soon as possible after each visit with a physician, encapsulating the visit." Id. at *8. The court in Zeneca Inc., then used the sales call notes as evidence that false advertising was taking place. Id. at *31. Similarly, in Abbott Labs. v. Mead Johnson & Co., 971 F.2d 6 (7th Cir. 1992), the court concluded that sales call notes "are the best evidence of what the representatives communicated to doctors during their detail visits." 971 F.2d at 10. The court in Pfizer, Inc. v. Miles, Inc., 868 F. Supp. 437 (D. Conn. 1994), also reiterated this concept, acknowledging the relevance of purported false statements when they were made by Pfizer sales representatives to medical professionals. Id. at 454. Here, the Court finds that the sales call notes, albeit vastly overstated in number by Bracco, are useful in determining whether false advertising occurred, and the extent to which it occurred in GEH's overall sales campaign. Similar to the sales call notes in Zeneca Inc., the Court finds the GEH sales call notes highly probative as to whether false advertising was occurring and to what proportion of the audience the allegedly false messages were being disseminated.

Second, to constitute "commercial advertising or promotion," challenged oral statements "must be disseminated sufficiently to the relevant purchasing public to constitute advertising or promotion within that industry." Seven-Up, 86 F.3d at 1384; G&B, 859 F. Supp. at 1535-36; see also J&M Turner v. Applied Bolting Tech. Prods., No. 95-2179, 1997 U.S. Dist. LEXIS 1835, at *49 (E.D. Pa. Feb. 18, 1997). While courts may disagree about whether the Lanham Act reaches certain

oral statements,[239] it is well-settled that the challenged statements, at the very least, must be "widely disseminated" and "part of an organized campaign to penetrate the relevant market." Fashion Boutique v. Fendi USA, Inc., 314 F.3d 48, 56-57 (2d Cir. 2002); Optimum Techs. v. Home Depot, 78 USPQ2d 1801, 1806 (N.D. Ga. 2005); see also Mario Valente Collezioni v. AAK Ltd., 280 F. Supp. 2d 244, 256-57 (S.D.N.Y. 2003). "Although advertising is generally understood to consist of widespread communication through print or broadcast media, 'promotion' may take other forms of publicity used in the relevant industry, such as displays at trade shows and sales presentations to buyers." Id. at 57; see, e.g., Seven-Up, 86 F.3d at 1386 (finding sales presentation to a significant percentage of industry customers constitutes advertising under the Lanham Act).

Here, GEH contends that the number of statements at issue is too small to be actionable. See Proctor & Gamble Pharms. v. Hoffmann-LaRoche Inc., No. 06-0034, 2006 WL 2588002, at *32 (S.D.N.Y. Sep. 6, 2006) (the court implied that 2% of call notes, which were made by a very small number of persons on the overall sales force, was a small percentage, noting that the company spoke to those representatives and confirmed that the proper sales message was being administered); Fashion Boutique, 314 F.3d at 65 (the court held that "twenty-seven oral statements regarding plaintiff's products in a marketplace of thousands of customers" was not actionable under the Lanham Act); Auto-Chlor Sys. of Minn., Inc. v. Johnson Diversey, 328 F. Supp. 2d 980, 1019-20 (D. Minn. 2004) (the court held that "three statements by Diversey-Lever representatives to three customers in a marketplace of hundreds of customers" is insufficient to show that the message was

[239] Sanderson, 415 F.3d at 624 (Lanham Act does not reach "oral statements and brochures at trade shows"); Schwarz Pharma, 388 F. Supp. 2d at 982; First Health Group v. BCE Emergis, 269 F.3d 800, 803-04 (7th Cir. 2001) ("an advertisement read by millions (or even thousands in a trade magazine) is advertising, while a person-to-person pitch by an account executive is not").

widely disseminated); Optimum Tech., 78 USPQ2d at 1806 ("here, isolated statements by sales personnel to individual customers do not satisfy the requirement of sufficient dissemination").

Conversely, Bracco relies on Florida Breckenridge, Inc. v. Solvay Pharm., Inc., No. 97-8417, 1998 U.S. Dist. LEXIS 14742 (S.D. Fla. Mar. 18, 1998), for the contention that the sales call notes are enough in number to constitute actionable representations to customers. In Florida Breckenridge, Inc., the court found that the oral statements in question "were . . . an integral part of Breckenridge's advertising campaign," holding that they constituted commercial advertising as a matter of law. Id. at *20-21. The court held that such oral statements were sufficiently disseminated to constitute advertising within the pharmaceutical drug industry, even though it was unclear how many times they were made. Id. at *21. The court relied on testimony from defendant's director of marketing, who stated: "I know of no business in the industry that promotes its prescription drugs without such face-to-face or personal attention on the part of the sales representative to the customer. In fact, in my experience, a prescription drug product could not be adequately promoted without such in-person and word-of-mouth promotion." Id. at *21.

The Court finds Florida Breckenridge, Inc. to be more analogous to the present case than the cases relied on by GEH because here the sales call notes were not made in isolation and were part of a large scale marketing plan to disseminate a message to its potential customers. Fashion Boutique, Auto-Chlor Sys. of Minn., Inc., and Optimum Tech. are inapposite because in each one of those cases, unlike the present case, the number of statements was either so small as to be insignificant or they were not part of an organized campaign to penetrate the relevant market. Here, it appears that the sales call notes, albeit limited in number, were only one part of a full-scale marketing plan by GEH to claim the benefits of Visipaque over LOCM alternatives, through sales

calls, websites, print marketing materials and more. The 87% number is greatly inflated, but even if the offending sales calls are a very small percentage, and thus, alone would not be actionable, when the sales calls are combined with GEH's overall campaign, which was promoted through press releases, websites, and CMEs, the result is false ads which have been sufficiently disseminated to be actionable under the Lanham Act.

GEH also contends that a good faith effort by a company to educate its sales force about what can fairly be said about published studies, such as GEH's training of the sales force and approval process for its promotional materials, renders any limited false or misleading statements made by representatives outside of those parameters not actionable. Proctor & Gamble, 2006 WL 2588002 at *32. However, the Court does not agree with the Defendants' reading of Proctor & Gamble. There the court did not base its ruling solely on Roche's efforts to educate its sales force; the ruling was based on the dispositive determination that the statements were not false or misleading in the first place. Id. Therefore, while the Court finds such training to be evidential, it is not dispositive.

iii. Website Ads, Print Ads in Newspapers, Magazines and Journals, Television Ads are Actionable Commercial Speech

Courts have applied the Lanham Act to just about every imaginable print and media form, including press releases, print ads, posters, and websites. See, e.g., Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co., 290 F.3d 578, 585-86 (3d Cir. 2002) (applying an injunction to advertisements on the defendants' website); Am. Home Prod., 871 F. Supp. at 744-45 (applying the Lanham Act to print advertisements in medical journals, TV commercials and print newspapers).

iv. Other Accused Materials as "Commercial Advertising or Promotion"

Bracco failed to adduce evidence that a Visipaque "protocol" was created or posted by GEH. Any such "protocol" is not "commercial advertising or promotion" because it was not sufficiently disseminated, if at all, to the relevant purchasing group or intended to influence purchasing decisions. However, CMEs sponsored by GEH are "commercial advertising or promotion," because although they are purportedly designed for educating the medical community and not influencing potential customers to buy goods or services, here they have been designed by GEH to deliver a specific message related to Visipaque renal superiority. See Neurotron, 189 F. Supp. 2d at 277. CMEs are customarily presented by physicians, but it appears that GEH, who sponsored certain CMEs, had a substantial role in the creation of the content of various CME presentations. For example, at trial, GEH's sales representative, Mr. Joseph Murray, confirmed delivering the Visipaque/NEPHRIC claims through the print media (e.g., press releases and articles) and CME-type presentations to customers in order to convert sales to Visipaque. (E.g., 16 T 31-49, 56-58, 81-88, 97-114; 17 T 49-51, 64-132). P2307 is one example of a CME which was sponsored by GEH, had the GEH logo on every slide, and was given by an authorized GEH representative. The Court finds such a CME - - created by GEH, sponsored by GEH, and presented by GEH representatives - - to be actionable under the Lanham Act because the direct control by GEH makes it commercial in nature, much akin to the scenario in Semco, where the court held that a trade article was actionable because the author was the manufacturer of the product. See Semco, 52 F.3d at 112. In addition, this type of CME presentation bears a resemblance to the informational mailings in Bolger, which contained product information, yet tried to veil their commercial nature by also including noncommercial speech about family planning. There, the court still held that the informational packet was actionable commercial speech. See Bolger, 463 U.S. at 67-68. Similarly, here the Court

finds that CMEs which were created by GEH, sponsored by GEH, and presented by GEH representatives are actionable commercial speech.

Another example of a GEH-sponsored CME, presented at least in part by GEH consultants, (Drs. McCullough and Davidson) states the following: "[R]ecent controlled trials have shown that *non-ionic Isosmolar contrast agents are superior to low-osmolar agents* in preventing CIN." (P4251:210) (emphasis added). "The use of iodixanol in at-risk patients appears to minimize the risk of CIN even without additional pharmacological prophylaxis." (P4251:212). This particular CME has the GEH logo on the first slide of the presentation and was presented, in part, by doctors who were paid consultants for GEH. (See P4251). Therefore, the Court finds that under the test promulgated in G&B, certain CMEs at issue in this case do in fact constitute commercial speech. This is strikingly similar to the circumstances in Semco, where the Court found the article at issue to be commercial advertising because the author was a biased member of the company selling the product for which the article touted superiority. Semco, 52 F.3d at 113-115. Here, by going through the G&B factors: (1) the CME is commercial advertising because similar to Semco the Court concludes that various CMEs were sponsored by GEH and presented by GEH consultants and tout Visipaque superiority, thus departing from the actual conclusions of the scientific studies upon which they are derived; (2) GEH is a direct competitor of Bracco; (3) the CMEs were put together for the purpose of influencing customers as their main message is Visipaque renal superiority over LOCM; and (4) the CMEs were widely disseminated as they were part of symposiums which were a component of an advertising campaign that spanned print, online, and phone. Therefore, the Court finds such CMEs containing the message that Visipaque is renally superior to LOCM to be actionable commercial speech under the Lanham Act.

3. GEH'S Representations are False and Misleading Under the Lanham Act

"Liability [under the Lanham Act] arises if the commercial message or statement is either (1) literally false or (2) literally true or ambiguous, but has the tendency to deceive consumers." Novartis Consumer Health, 290 F.3d at 586 (citing Castrol, 987 F.2d at 943 ("a plaintiff must prove either literal falsity or consumer confusion, but not both") (emphasis in original)). The focus of a Lanham Act inquiry is whether statements "are false or misleading at the time they are made." Alpo Petfoods, Inc. v. Ralston Purina Co., 720 F. Supp. 194, 205 n.12 (D.D.C. 1989) ("Post facto evidence cannot make actionable true claims which later become false and does not bar suits for false or misleading representations which later become true."), rev'd in part on other grounds, 913 F.2d 958 (D.C. Cir. 1990); Satis Vacuum Indus. Vertriebs, AG. v. Optovision Tech., Inc., No. 99-2147, 2001 WL 1142803, at *10 (N.D. Tex. Sept. 24, 2001). The Court will address Bracco's claims under each theory of liability.

a. Puffery

Under the Lanham Act, nonspecific statements that do not refer to specific characteristics of a product are nonactionable puffery. See Nikkal Indus., Ltd. v. Salton, Inc., 735 F. Supp. 1227, 1234 n. 3 (S.D.N.Y.1990) (General claims that the product was "better" were mere puffery and not actionable as false advertising.); United States Healthcare, 898 F.2d at 926 (In the context of the advertising in the case, the defendant's claim that it was the better health care plan was an innocuous kind of puffery.). "Puffery is distinguishable from misdescriptions or false representations of specific characteristics of a product. As such, it is not actionable." Castrol, 987 F.2d at 945-46; see Stiffel Co. v. Westwood Lighting Group, 658 F. Supp. 1103, 1115 (D.N.J.1987). Bracco contends

that GEH's claims are not puffery and that they are actionable under the Lanham Act. The Court finds that GEH's allegedly false claims that explicitly or implicitly address product attributes of importance to customers and make statements that are measurable by comparative research are not puffery. See Castrol, 987 F.2d at 945-46 (holding that Penzoil's claim of superior engine protection was more than mere puffery because "it is both specific and measurable by comparative research"); see also Stiffel Co., 658 F. Supp. at 1115 (claims to superiority flowing from purported independent tests, are more than puffery); Genderm Corp. v. Biozone Labs., No. 92-2533, 1992 U.S. Dist. LEXIS 13521, at *42 (N.D. Ill., Sept. 3 1992) (false descriptions of clinical trial results are not puffery); Am. Home Prods. v. Johnson & Johnson, 654 F. Supp 568 (S.D.N.Y. 1987) (claim that Tylenol gives unsurpassed relief is not puffery).

In addition, false claims are not excused or remedied by the use of footnotes because "a footnote or disclaimer that 'purports to change the apparent meaning of the claims and render them literally truthful, but which is so inconspicuously located or in such fine print that readers tend to overlook it, will not remedy the misleading nature of the claims." SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharm. Co., 906 F. Supp. 178, 182 (S.D.N.Y. 1995) (citing Am. Home Prods. v. Johnson & Johnson, 577 F.2d at 167); McNeilab, 654 F. Supp. 568, 590 (S.D.N.Y. 1987), aff'd, 100 F.3d 943 (2d Cir. 1996)); Cuisinarts, Inc. v. Robot-Coupe Int'l Corp., 509 F. Supp. 1036, 1044 (S.D.N.Y. 1981). In this case, GEH used footnotes after its claims, which provided alleged support for the statements, by citing to studies or articles, without further explanation. Even if footnotes could make a significant difference, GEH's footnotes never cite to the weight of the clinical evidence, GEH's other unpublished studies, and

perhaps most compellingly, other study results and limitations in its own studies. Thus, the footnotes do not excuse any claims that are false or misleading.

b. Unclean Hands

Moreover, GEH's claims, which have significant safety implications (Pl.'s FOF ¶ 87, n. 88), are not excused by any allegations that Bracco has unclean hands. GEH asserts that Bracco has unclean hands because it is allegedly inflating its damages claim beyond all reason, and engaging in its own alleged campaign of false advertising against Omnipaque. (See Answer ¶¶ 96-101). The Court notes that such a defense is rarely successful due to "a strong public interest in the prevention of misleading advertisements." Am. Home Prods. Corp., 654 F. Supp. at 590 (citing Coca-Cola Co. v. Tropicana Prods., Inc., 690 F.2d 312, 317 (2d Cir. 1982)). As such, "a defense of unclean hands can be established only by 'clear, unequivocal and convincing' evidence." Id. (quoting Nike, Inc. v. Rubber Mfg. Ass'n, Inc., 509 F. Supp. 919, 926 (S.D.N.Y. 1981)). Furthermore, when public health is at issue, as in false drug advertising, the unclean hands defense must be "judiciously applied." McNeilab, 501 F. Supp. at 539.[240] Bracco's alleged misconduct, even if taken as true, was, done for largely defensive purposes, limited in scope and duration; it does not create an unclean hands defense.

c. Literal Falsity

[240] An unclean hands defense also requires that a plaintiff must have engaged in precisely the same behavior it accuses the defendant of conducting. See, e.g., Specialty Minerals, Inc. v. Pluess-Staufer AG, 395 F. Supp. 2d 109, 112-13 (S.D.N.Y. 2005) (rejecting the defense because "factually similar misconduct alone is [not] sufficient to create the necessary link"); Citizens Fin. Group Inc. v. Citizens Nat'l Bank, 383 F.3d 110, 129 (3d Cir. 2004) ("'the extent of actual harm caused by the conduct in question, either to the defendant or to the public interest, is a highly relevant consideration.'") (citations omitted).

In Novartis, the Third Circuit clearly set out the framework for making a determination of literal falsity:

> In analyzing whether an advertisement or product name is literally false, a court must determine, first, the unambiguous claims made by the advertisement or product name, and second, whether those claims are false. Clorox Co. v. Proctor & Gamble Commercial Co., 228 F.3d 24, 34 (1st Cir. 2000). A "literally false" message may be either explicit or "conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated." Regardless, only an unambiguous message can be literally false. "The greater the degree to which a message relies upon the viewer or consumer to integrate its components and draw the apparent conclusion, however, the less likely it is that a finding of literal falsity will be supported." United Indus. Corp. v. Clorox Co., 140 F.3d 1175, 1181 (8th Cir.1998); see Warner- Lambert Co. v. BreathAsure, Inc., 204 F.3d 87, 96 (3d Cir.2000); Castrol, 987 F.2d at 946; see also Cuisinarts, Inc. v. Robot-Coupe Int'l Corp., [No. 81-731,] 1982 WL 121559, at *2 (S.D.N.Y. June 9, 1982).

Novartis, 290 F.3d at 586-87. Furthermore, when determining whether a claim is literally false, audience sophistication is irrelevant. JR Tobacco of America, Inc. v. Davidoff of Geneva (CT), Inc., 957 F. Supp. 426, 432 (S.D.N.Y. 1997) (citing Merck Consumer Pharmaceuticals, 960 F.2d at 298 (listing factors to be used in determining whether an advertisement is likely to mislead or confuse public, not literal falsity)); see Morgenstern Chem. Co. v. G.D. Searle & Co., 253 F.2d 390, 393-94(3d Cir. 1958) (declining to take into account customer sophistication in particular industry when determining whether there is a likelihood of confusion between two trademarks).

The first step in analyzing whether GEH's renal and non-renal superiority claims are literally false requires the Court to determine the unambiguous claims used in GEH's advertising. Here, the renal claims being made by GEH can be categorized into three messages: "Visipaque may be better than a LOCM," "Visipaque is better than all LOCM,"[241] and "Visipaque is as good as or better than

[241]Some indicative phrases of GEH's claims of Visipaque's renal superiority over all LOCM, as discussed supra are: (1) "[]The NEPHRIC data clearly demonstrate that Visipaque™ offers a

a LOCM with prophylactics."[242] The claims asserted in the last two statements are unambiguous, however the meaning of the first statement has garnered substantial argument from the parties in this case. The first claim is paraphrased from the conclusion of the NEPHRIC study[243] and without the context of the study may be subject to interpretation and be misleading. This is primarily because the study compared one iso-osmolar CM (Visipaque) with only one low-osmolar CM (Omnipaque), not all low-osmolar CM. Thus, when the conclusion is read in conjunction with the entire article, it could be taken to mean that Visipaque is only better than the LOCM tested in the study, namely Omnipaque. Nonetheless, when the conclusion of the NEPHRIC study is distributed secondarily in advertising, without the benefit of the study results, the Court finds that it projects a misleading message that Visipaque may be better than all LOCM, even those not tested in the NEPHRIC study.

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significantly better renal safety profile than traditional low osmolar non-ionic contrast media in at-risk patients… We believe that the data strongly support Visipaque™ as the agent of choice for these patient groups." P2449:379, P69:915, P254:863, P772:340, P1448:898, P4149:p2; 7 T 68-69; (2) [C]linicaI studies, nephric etc show less risk nephrotox vs ... Isovue for [high risk] pts ...." P2312:A659673, P4049:A659673; (3) "Approached dr. with nephric focus and differentiating vis from locm class with regards to osmoality. Reminded dr. that patients are 11 times likely to have CIN with the locm class than visi." P3682:Omni/3727, 4049:Omni/3727; and (4) "[R]ecent controlled trials have shown that *non-ionic Isosmolar contrast agents are superior to low-osmolar agents* in preventing CIN." P4251:210 (emphasis added).

[242] An example of GEH's claims of Visipaque's renal superiority over LOCM with prophylactics, as discussed supra is: "I…discussed the attributes of Isosmolar Visipaque including it's impact on CIN -- a clinical issue just coming to light; it's elimination of costly drug therapies (fenladopan) to prevent CIN with std LOCM." P793:514.

[243] The NEPHRIC conclusion actually states: "[n]ephropathy induced by contrast medium may be less likely to develop in high-risk patients when iodixanol [(an iso-osmolar contrast medium)] is used rather than a low-osmolar, nonionic contrast medium." P2467.

GEH's non-renal superiority claims can be categorized into the following messages: (1) cardiovascular superiority, (a) Visipaque causes lower incidence of MACE than LOCM;[244] (b) Visipaque causes less discomfort-type (i.e., claiming less pain, warmth, discomfort or patient movement or designed for such);[245] (2) osmosality/cost superiority, (a) Visipaque performs better than LOCM because of lower osmosality and associated costs as a result.[246]

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[244]Some examples of GEH's claims of Visipaque's superior performance with regard to incidence of MACE over all LOCM, as discussed supra are: (1) "Abstract Shows Significantly Lower Incidence of [Major Adverse Cardiac Events or Major Adverse Clinical ("MACE")] Following [PCI] Using Visipaque Compared to Isovue.…" P2669:480, P3114H:857-58, P1893:940-41, P4151:p2; 7 T 69; (2) "Visipaque doesn't increase heart rate or B/P like LOCM". P3682:Omni/38573, 4049:Omni/38573; and (3) Nonionic Dimer Provides Reduced MACE …" P410:965, P3649:408, P3649A:408, D2324:117.

[245]Some examples of GEH's claims of Visipaque's superior performance with regard to patient discomfort over all LOCM, as discussed supra are: (1) "[Visipaque] offers significantly better comfort to the patient…" P2508:767A, P2511C:781A, P4163:767A, P4166C:781A; (2) "She asked why use Vis Shared theory isosmolar, less fluid shifts and thus less pt discomfort, movement and need to rescan...." P2312:A650688, P4049:A650688; and (3) "Less chance of extravasation-related complications — including pain, discomfort…when used:" "Less chance of patient discomfort…when used in:" "High concentration", "High-rate injections", "Multiple procedures", "High-speed procedures." P410:966.

[246]Some examples of GEH's claims of Visipaque's superior performance with regard to osmosality/cost over all LOCM, as discussed supra are: (1) Showing "hyperosmolality" (i.e., osmolality higher than blood, like Isovue) leading to "altered morphology" of "erythrocytes" and "endothelial cells", ultimately leading to "discomfort", "warmth", "coldness" and "pain." P2508:766A, P2511C:781A, P4163:766A, P4166C:781A; see also P3114K:823, P2510:771A, P2508:763A, P2511C:779A, P4163:763A, P4165:771A, P4166C:779A, P2183:982, P2184:000, P2311:p4, P2298:p25, P4252:p3, P3828:929, P3261:011, P3829:036, P2156:036, P2157:212. Additional claims of less red blood cell effect of IOCM vs. LOCM can be found at: P2311:p5, P3710:p2, P2280:p5, P395:357, P409:945, P333:738, P410:960, P3649:403, P3649A:403, P436A:421, 27-28, P2298:p7, 13-14, P782:893, P2161:387, P2183:991, P2184:009, P4252:p12, P4174:p1, P3114J:821, P3210:934, 410:962, P3649:405, P3649A:405, P2510:772A, P2508:764A-65A, P2511C:780A, P4163:764A-65A, P4165:772A, P4166C:780A; D2324:114, D2334:p2, D2324:112; (2) "Isosmolar VISIPAQUE may reduce financial burden due to serious adverse events". P446:641, P649:665; and (3) "Used the 'cost' story for Visi vs. LOCM....." P3682:Visi/154349, P4049:Visi/154349.

Second, the Court must determine if the unambiguous statements are literally false. The type of proof needed to prove literal falsity varies with the type of advertising claim being made. Novartis, 290 F.3d at 586-87; Castrol, Inc. v. Quaker State Corp., 977 F.2d 57, 63 (2d Cir. 1992). Claims that do not mention tests must be affirmatively proven false, whereas establishment or "tests prove" claims can be challenged by "demonstrating that the tests were not sufficiently reliable" to permit the conclusion reached or by showing that "the tests, even if reliable, do not establish the proposition asserted." Rhone-Poulenc Rorer Pharms. v. Marion Merrell Dow, 93 F.3d 511, 515 (8th Cir. 1996) (holding that in analyzing "tests prove" claims, courts "should give advertisers a fair amount of leeway," in order "[t]o ensure vigorous competition and to protect legitimate commercial speech"). There are two types of comparative advertising campaigns that typically become the subject of a Lanham Act false superiority claim. Marion Merrell Dow, 93 F.3d at 514-15. The first constitutes a bald assertion of superiority, in essence: "my product is better than yours." Id. at 514. The second occurs when an ad campaign relies on scientific testing or studies to support the claim of superiority: "tests or studies prove that my product is better than yours." Id. To establish literal falsity of the second type of superiority claim, which is at issue here,[247] "a plaintiff must do more

[247]GEH argues that Bracco improperly characterized its marketing as "tests prove" claims. However, the Court finds that there is an abundance of evidence to show that GEH's promotional campaign was primarily based on establishment type claims of superiority. Further, GEH contends that Bracco bears the burden of proof through surveys to show that GEH's claims were establishment claims and not just regular superiority claims citing to L & F Products v. The Proctor & Gamble Co., 845 F. Supp. 984 (S.D.N.Y. 1994), and C.B. Fleet Co. v. SmithKline Beecham Consumer Healthcare, L.P., 131 F.3d 430 (4th Cir. 1997). In L & F Products the court held that plaintiff "failed to produce persuasive evidence, such as consumer surveys, that consumers believed that the [ads] depict tests or studies." 845 F. Supp. at 1000-01. In C.B. Fleet Co., the Court concluded that "whether an advertising claim implicitly, though not expressly, asserts that it is test-validated must be considered [a] question of fact…. The relevant question for determining the required proof is whether the advertisement made an assertion of test-validation to the consumer public." 131 F.3d at 436.

than show that the tests supporting the challenged claim are unpersuasive." Castrol Inc. v. Pennzoil Quaker State, 169 F. Supp. 2d 332, 336 (D.N.J. 2001); see McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co., 938 F.2d 1544, 1549 (2d Cir.1991); Procter & Gamble Co. v. Chesebrough-Pond's, Inc., 747 F.2d 114, 119 (2d Cir.1984).

Bracco contends that GEH's renal representations (Pl.'s FOF ¶¶ 2-9) and non-renal representations (Pl.'s FOF ¶¶ 18-22) for Visipaque are establishment claims that either explicitly or implicitly reference tests, data, charts, and clinical trials and/or use terms such as "proven" or "establish." See, e.g., Glaxosmithkline Consumer Healthcare, L.P. v. Merix Pharm. Corp., No. 05-898, 2005 WL 2230318, at *3 (D.N.J. Sept. 13, 2005), aff'd, 197 Fed. Appx. 120 (3d Cir. 2006); Glaxo Warner OTC G.P. v. Johnson & Johnson Merck Consumer Pharm. Co., 935 F. Supp. 327, 329 (S.D.N.Y. 1996). Accordingly, in this case, the Plaintiff must show that the underlying studies upon which the representations are based are "not sufficiently reliable to permit one to conclude with reasonable certainty that they established the claim made." McNeil-P.C.C., 938 F.2d at 1549 (internal quotation omitted). There are two ways for plaintiff to carry this burden: either by successfully assailing the validity of the underlying study; or by showing that the study results are

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Nonetheless, those cases are inapposite because in each one of them, it was not clear that the superiority claim was based on a test. For example in L & F Products, the Court found that the advertisements in question unambiguously depicted demonstrations of the two competing products by actors in a studio, not a laboratory test conducted by technicians. 845 F. Supp. at 1000-01. Similarly, in C.B. Fleet Co., the court stated that the plaintiff must prove consumer perception of a "tests prove" superiority claim when the message is implicit. 131 F.3d at 436. Conversely, in this case GEH's marketing campaign was focused on disseminating the conclusions of the NEHPRIC study and it advertised itself as being a part of the NEPHRIC study. There is no ambiguity, and the Court finds GEH's advertising campaign to be explicit in its "tests prove" message. Therefore, the Court finds that no survey is required to prove that the advertising consisted of "tests prove" type claims.

undermined by other scientific studies. Castrol Inc., 169 F. Supp. 2d at 336; McNeil-P.C.C., 938 F.2d at 1549; see also Quaker State, 977 F.2d at 62-63 (distinguishing product superiority claim not based on testing, which must be proven false by affirmative evidence, from product superiority claim explicitly or implicitly based on tests or studies which may be proven false by showing that the tests did not establish the proposition for which they were cited). "Moreover, if the plaintiff can show that the tests, even if reliable, do not establish the proposition asserted by the defendant, the plaintiff has met its burden of demonstrating literal falsity." Castrol Inc., 169 F. Supp. 2d at 336; Quaker State, 977 F.2d at 63.

Bracco further contends that GEH has made a claim in its advertising that "Visipaque is better than all LOCM," and that this statement is literally false and unsupported by the findings of the NEPHRIC study. (See Pl.'s FOF ¶¶ 10-17, 23-39). In the alternative, Bracco asserts that the studies upon which GEH based its representations are unreliable (including NEPHRIC, COURT, and VICC) and are contradicted by the weight of the pertinent scientific evidence. (Id.) With regard to the first allegation, the Court finds that GEH's representation, that "Visipaque is better than all LOCM," is an extrapolation which strays too far from the results and conclusions of the underlying NEPHRIC, COURT, and VICC studies. See supra pp. 24-41. In regard to the second allegation, the Court finds that the NEPHRIC, COURT and VICC studies are reliable, to the extent that their conclusions state that Visipaque *may* perform better than a LOCM, for certain patient groups,[248]

[248]Again, the varied relevant studies tested different patient groups. The NEPHRIC study focused on high risk patients and incidents of CIN when using Visipaque versus Omnipaque. In COURT, scientists compared the use of Visipaque and Hexabrix in high risk patients undergoing Percutaneous Transluminal Coronary Angioplasty ("PTCA") to determine which CM gave rise to more incidents of in-hospital MACE. VICC looked at patients from all risk levels, specifically those patients undergoing percutaneous cardiac intervention ("PCI"), to document incidents of MACE, comparing Isovue and Visipaque. VICC confirmed the findings of COURT in light of

however, for GEH to redistribute the study conclusions, without clearly and prominently identifying the drugs compared in each of the studies, presents a misleading message to the public. GEH must caveat the quoted or paraphrased conclusions by clearly and conspicuously stating which drugs were actually tested in the studies. This approach produces an equitable result because the Court finds that the underlying data of the studies are not vitiated by the flaws Bracco identifies. Thus, GEH may use NEPHRIC and similar studies in its advertising as long as the actual drugs tested, identified by brand name, are plainly and conspicuously disclosed – not simply in a footnote or small print – and it is disclosed that other LOCM were not tested.[249] At that point, consumers can make an informed decision as to how much weight to accord a certain study. Finally, GEH may not explicitly or implicitly, through its sales representatives, communicate Visipaque superiority over Isovue unless a reliable head to head trial between these products supports such a contention.

Nonetheless, despite the Court's finding that NEPHRIC, COURT and VICC are reliable regarding their conclusions as to the administration of CM alone, the Court finds that the articles are not reliable for the assertion that "Visipaque is better than (or superior) to LOCM with prophylactics." This conclusion is simply not adequately supported by any studies, as discussed supra, pp. 24-41.

i. Impact of FDA on Standard for Determining Literal Falsity

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changes in practice, specifically the use of more stents and more IIB/IIIA inhibitors.

[249]In addition, in correspondence to GEH as recently as March, 21 2005, the FDA has echoed similar caveats regarding the unsupported contention that Visipaque performs superior to all LOCM. P1894.

Bracco contends that the falsity of the claims is further confirmed by the findings of the FDA. (Pl.'s FOF ¶¶ 11, 24, 31, 37). The "FDCA or FDA regulations may be utilized in a Lanham Act action to 'establish the standard or duty which defendants allegedly failed to meet.'" Genderm Corp. v. Biozone Labs., No. 92-2533, 1992 U.S. Dist. LEXIS 13521 (N.D. Ill., Sept. 3 1992) (quoting Grove Fresh Dist., Inc. v. Flavor Fresh Foods, Inc., 720 F. Supp. 714, 716 (N.D. Ill. 1989)). Furthermore, courts have consistently held that the FDA's scientific findings are not only relevant, but entitled to significant deference. See, e.g., Zeneca, 1999 WL 509471, at *33-34. Here, GEH conceded the probity of the FDA's determinations. (7 T 5-6).

Courts have likewise rejected arguments that would require them to second-guess the expert judgment of the FDA. See, e.g., Thompson Med. Co. v. Ciba-Geigy Corp., 643 F. Supp. 1190, 1193 n.5 (S.D.N.Y. 1986); SmithKline Beecham Consumer Healthcare v. Johnson & Johnson-Merck, No. 95-7011, 1996 WL 280810, at *13 (S.D.N.Y. May 24, 1996). GEH responds by arguing that the Lanham Act cannot be used to redress perceived violations of the Food, Drug, and Cosmetic Act ("FDCA"), and that it is improper "for a court in a Lanham Act case to determine preemptively how the FDA will interpret and enforce its own regulations." Sandoz, 902 F.2d at 231; 21 U.S.C. § 337; Eli Lilly, 23 F. Supp. 2d at 476-77; see also Gile v. Optical Rad. Corp., 22 F.3d 540, 544 (3d Cir. 1994). Contrary to GEH's assertions, the Court here is not speculating as to how the FDA might opine since the FDA has flagged its views through numerous letters to GEH regarding the misleading nature of Visipaque superiority claims.

Furthermore, Bracco asserts that the FDA's failure to take action against GEH and its ads is irrelevant because (a) GEH never proved that it sent its ads to the FDA; (b) courts consistently refuse to infer agency adoption based on mere inaction (Providence Journal Co. v. United States Dep't of

the Army, 981 F.2d 552, 558 (1st Cir. 1992)); (c) the FDA's silence as to particular ads is not a valid defense (In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig., No. 05-1699, 2006 WL 2374742, at *11 (N.D. Cal. Aug. 16, 2006)); and (d) GEH conceded the point. (7 T 8). GEH responds by arguing that Bracco tried, without success, to convince the FDA to take action against GEH for the same alleged statements that Bracco argues are false and misleading in this case and that Bracco now urges this Court to take action where the FDA has not.[250] GEH contends that to use statements in a non-final FDA letter, that issued based on Bracco's lobbying and before GEH had an opportunity to be heard, is premature. GEH relies on a series of cases that rejected attempts to use the Lanham Act as a backdoor for private enforcement of the FDCA, with courts dismissing false advertising claims that stray "too close to the exclusive enforcement domain of the FDA." Schering-Plough, 547 F. Supp. 2d at 943-44, 948 (marketing and labeling of prescription drugs are properly addressed to the FDA, not the courts); Schwarz Pharma, 388 F. Supp. 2d at 974 (courts should not interfere with the FDA's investigatory timetable and prosecutorial decision-making); Summit, 922 F. Supp. at 306; Sandoz, 902 F.2d at 231.

However, the Court finds those cases to be inapposite because here the Court is not seeking to usurp the FDA's authority or preempt its findings in an ongoing investigation. Furthermore, the Court finds the circumstances in Zeneca, as opposed to the cases cited by GEH, to be more

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[250] None of the FDA letters introduced by Bracco at trial constitute final agency action, and none found any specific GEH ad or promotional piece to be false or misleading. See Schering-Plough Healthcare Prods. v. Schwarz Pharma, 547 F. Supp. 2d 939, 946-47 (E.D. Wis. 2008) (informal and tentative letters issued by the FDA do not constitute formal or final agency action requiring deference); Dietary Supplement Coalition v. Sullivan, 978 F.2d 560, 562-63 (9th Cir. 1992); Genendo Pharm. N.V. v. Thompson, 308 F. Supp. 2d 881, 884-85 (N.D. Ill. 2003); Summit Tech. v. High-line Medical Instruments, 992 F. Supp. 299, 306 (C.D. Cal. 1996).

analogous to this case. There, the court addressed the issue of an ongoing dialogue with the FDA regarding a peer reviewed study resulting in multiple non-final letters:

> Eli Lilly also suggests that the dialogue with the FDA is still ongoing and that the findings and opinions set forth in the January 1999 minutes with respect to MORE, and the May 1999 minutes with respect to MORE and CORE, do not reflect the agency's last word on the subject or are an incorrect recitation of the FDA's position. This argument is contradicted by the FDA's repeated statements over a two-year period. And whether or not the dialogue is ongoing, the FDA has made abundantly clear that MORE-either alone or in conjunction with CORE does not and cannot prove that Evista reduces the risk of breast cancer.

Zeneca, 1999 WL 509471 at *27. Similar to the dialogue with the defendant in Zeneca, here the FDA has also consistently sent letters to GEH, over the course of many years, advising that GEH cannot make a Visipaque superiority claim. Furthermore, there is no indication of an ongoing dialogue. Accordingly, there is no compelling reason for this Court to delay its decision or defer this action to the FDA; it is properly within the scope of the Lanham Act and the province of this Court.

Nonetheless, the Court notes that Bracco cannot prove falsity simply by relying on statements made in FDA letters that apply FDA standards. A Lanham Act plaintiff must do more than assert that the challenged claims "are inadequately substantiated under FDA guidelines; the plaintiff must also show that the claims are literally false or misleading to the public." Sandoz, 902 F.2d at 224, 229 (FDCA serves a different purpose and applies different standards to advertising and promotion than the Lanham Act); J&J-Merck, 19 F.3d at 130; AstraZeneca, 444 F. Supp. 2d at 295. As Bracco's FDA expert, Mr. Pines, admitted, the FDA requires at least two adequate and well-controlled studies comparing the same two products for a superiority claim, and thus imposes a more stringent standard than that applicable under the Lanham Act. (14 T 216:10-217:2, 218:12-220:3;

15 T 43:1-7). However, in this case, Bracco has not relied solely on the FDA, but has put forth other arguments in support of a finding that GEH disseminated false messages in its advertising.

1. The Conclusions of the NEPHRIC Study as Reported in the New England Journal of Medicine

To begin, the Court will discuss the relevance of the NEPHRIC study to determine if GEH's claims that "Visipaque is better than all LOCM," "Visipaque may be better than a LOCM," and "Visipaque is as good as or better than a LOCM with prophylactics" are supported by NEPHRIC's conclusions or whether the representations are unsupported by the study conclusions, thus making them literally false. The NEPHRIC study reported in the NEJM, (P2467), only compared Visipaque to Omnipaque, not Visipaque to all LOCM (or Isovue). Bracco avers that, because the NEPHRIC study only compares Omnipaque to Visipaque, GEH's claims that "Visipaque is better than all LOCM" is not a conclusion of the study and that the claim that "Visipaque is better than a LOCM" is only true for Omnipaque, and thus, does not apply to Isovue or any other LOCM since no other LOCM was the subject of the study. Bracco further avers that the NEPHRIC study did not even test the use of a LOCM with prophylactics, and therefore, does not support a claim that Visipaque is as good as or better than a LOCM with prophylactics.

The Court agrees with Bracco's reading of the conclusions in the NEPHRIC study. The NEPHRIC study concludes that "[n]ephropathy induced by contrast medium may be less likely to develop in high-risk patients when iodixanol [(an iso-osmolar contrast medium)] is used rather than a low-osmolar, nonionic contrast medium." (P2467). The study concludes that nephropathy *may* be less likely to occur; this is different from what GEH advertises: that renally, iso-osmolar contrast mediums (the equivalent of saying Visipaque because it is the only iso-osmolar CM on the market)

are better than low-osmolar, nonionic contrast mediums in high risk patients. Isovue is a low-osmolar, nonionic contrast medium, as is Omnipaque, the one tested in the NEPHRIC study, and Visipaque is an iso-osmolar contrast medium, which was the CM actually tested in the study. Therefore, the Court finds that based on the conclusions of the NEPHRIC study there is no support for GEH to represent that "Visipaque is renally better than all LOCM" and "Visipaque is better than a LOCM," because the NEPHRIC study conclusion only states that Visipaque *may* be better than a LOCM. Even then, GEH must give context to the statement by including language that identifies which products, by brand name, were actually tested in the study. In addition, the conclusion reached in the NEPHRIC study, i.e., that the Visipaque results "were similar to or better than those in studies that included low-osmolar contrast mediums and [prophylactic pharmacologic regimens]" (P2467:917), is inadequately supported, and thus, the study is unreliable for this claim. Accordingly, GEH's claims of superiority, as set forth above, are determined to be literally false due to unsupported representations and misstated conclusions.

2. The NEPHRIC Study

Bracco asserts, in the alternative, that even if GEH's representations are supported by the conclusions of the NEPHRIC study, the study itself was unreliable and is undermined by other scientific studies supporting a determination of literal falsity for GEH's superiority claims. Bracco began its attack on the NEPHRIC study by presenting testimony which it claims establishes that NEPHRIC was not designed to test whether osmolality is responsible for CIN, (20 T 6) and that its conclusions were never repeated in an adequate and well-controlled study.[251] In addition, Bracco

[251] The Court notes that the requirement that the results be repeated in an adequate and well-controlled study is not the standard of the Lanham Act and merely reflects FDA requirements.

also contends that NEPHRIC provided no support for the claim that Visipaque is as good as or better than a LOCM with prophylactics and does not represent the weight of the scientific evidence. (See, e.g., P2467; 3 T 89-90).[252] Dr. Solomon testified, and GEH did not rebut, that Table IV of the NEPHRIC article, which purports to present results from other studies, is inaccurate and misleading because it incorrectly reports the results of the studies. (3 T 126-131; P3148, P37, P2053, P2386, P2390). Bracco states that Table IV is also inaccurate and misleading because it does not report the contradictory results of GEH's internal data, which were not reported in the NEPHRIC study.[253]

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[252]Bracco supports this assertion by stating that none of the cited studies in the NEPHRIC article used pretreatments. See P2467:916-7.

[253]During this litigation, evidence showed that GEH concluded a study called "NEPHRIC II," where it compared Visipaque and Isovue head-to-head. Despite the obvious relevance of such a study, GEH has not produced documents concerning it (Dr. Davidson produced the protocol pursuant to a third party subpoena). Bracco asks the Court to draw an inference that this study showed that Isovue was at least equivalent to Visipaque. However, the Court declines to do so in the absence of any evidence of its actual results. Furthermore, in 2007, GEH moved to stay the case, reopen discovery and produce NEPHRIC II documents, along with those from Bracco's ongoing PREDICT study, which compared Visipaque and Isovue. Bracco opposed the motion, and the Court denied it. Therefore, the Court declines to revisit this issue or draw an inference for either party.

Nonetheless, the Court notes that such a study and its results would be of use to the Court in its determination to issue an injunction because despite the rule that new study results are only relevant to whether subsequent ads "are false or misleading," in this case the alleged violative conduct is ongoing. See Alpo Petfoods, 720 F. Supp. at 205 n.12 ("Post facto evidence cannot make actionable true claims which later become false and does not bar suits for false or misleading representations which later become true."), rev'd in part on other grounds, 913 F.2d 958 (D.C. Cir. 1990); Satis Vacuum Indus. Vertriebs, AG. v. Optovision Tech., Inc., No. 99-2147, 2001 WL 1142803, at *10 (N.D. Tex. Sept. 24, 2001). Since the alleged violative conduct is ongoing, even if such results would not affect whether the ads disseminated before the completion of the study constituted false advertising, such results would be relevant to the Court's analysis of whether an injunction should issue. However, the subsequent study results are not before the Court.

The Court finds that these contentions do more than "show that the [NEPHRIC Article] supporting the challenged claim [is] unpersuasive." Castrol Inc., 169 F. Supp. 2d at, 336; see McNeil-P.C.C., 938 F.2d at1549; Procter & Gamble, 747 F.2d at 119. As stated above, Bracco bears the burden of establishing that the underlying studies upon which GEH's representations are based are "not sufficiently reliable to permit one to conclude with reasonable certainty that they established the claim made." McNeil-P.C.C., 938 F.2d at 1549 (internal quotation omitted). It is not dispositive that the NEPHRIC article misstated certain test criteria from other articles because the relevant inquiry is whether the NEPHRIC study and its test data are sufficiently reliable to support NEPHRIC's conclusions. Here, the Court determines that NEPHRIC is reliable for its conclusion that Visipaque *may* perform better renally, in high-risk patients, than *a* LOCM, that LOCM being Omniqaque, but unreliable for the conclusion that Visipaque may or does perform better than LOCM with prophylactics.

The NEPHRIC study was a head-to-head study between Omnipaque and Visipaque, albeit not Visipaque and all, or even more than one LOCM, but the study does go through some analysis as to why such results may apply across all LOCM. Therefore, the Court concludes that while GEH cannot rely on NEPHRIC to advertise that Visipaque performs better than all LOCM, it can redistribute the NEPHRIC article as long as it is clear in the advertising that the study was a head-to-head comparison, using Omnipaque and Visipaque, not any other LOCM or all LOCM. Not surprisingly, the FDA agrees that NEPHRIC cannot support a statement that Visipaque is renally superior to all LOCM. (P1894).

As to whether the NEPHRIC article's conclusion, "the use of iodixanol alone may eliminate many of the effects or logistic problems created when prophylactic pharmacologic regimens are

used," is unsupported by its results is a more involved inquiry. The NEPHRIC study did not test any LOCM with prophylactics, but the conclusion stops short of stating the proposition that iso-osmolar contrast mediums will be more effective than nonionic low-osmolar contrast mediums with prophylactics in preventing CIN. The article merely states that using iso-osmolar contrast mediums would eliminate some logistical and adverse side effects associated with the use of low-osmolar contrast mediums combined with prophylactics. The NEPHRIC study need not test low-osmolar contrast mediums with prophylactics to demonstrate the tautology that the absence of the prophylactics would cure any logistical or adverse side effects produced by the prophylactics themselves. Nonetheless, because the NEPHRIC study does not actually test LOCM with prophylactics, it is literally false for GEH to state that Visipaque is as good as or better than a LOCM with prophylactics based on the NEPHRIC article. Accordingly, the Court finds that the NEPHRIC article and its accompanying conclusions do not stand for the propositions that (1) Visipaque is better than all LOCM or (2) Visipaque is better than a LOCM with prophylactics. Nonetheless, the Court finds that GEH may state in its advertising that Visipaque *may* be better renally than a LOCM in high-risk patients only if that same printed advertising plainly and conspicuously reveals that NEPHRIC was a head-to-head study between Visipaque and Omnipaque and that the conclusion of NEPHRIC is limited to the tested product, or when relying on any other study, the actual CM compared; additionally, any sales calls or other oral presentations which discuss the NEPHRIC conclusions or other studies must disclose the actual comparative drugs in the study, and it must be made clear that extrapolation to other LOCM is not established by the study.

ii. FDA's Input on the NEPHRIC Study is Persuasive Evidence of its Unreliability For Renal Superiority Claim as to All LOCM

The Court finds persuasive that GEH's primary endpoint in the NEPHRIC study, mean peak change, was rejected as a meaningful or reliable measure by the FDA and GEH's Dr. Feldman. (Pl.'s FOF ¶¶ 11,13). This lends credence to the Court's finding that NEPHRIC cannot reliably support GEH's Visipaque renal superiority claim and thus prevents GEH from using the NEPHRIC article as a reliable means to support its claim of renal superiority over all LOCM. See, e.g., Abbott Lab. v. Mead Johnson & Co., No. 91-202, 1991 U.S. Dist. LEXIS 21010, at *105 (S.D. Ind., Oct. 10, 1991) (rejection of study data as not clinically meaningful); Quaker State, 977 F.2d at 64 (holding that a claim of superiority was false when defendants' tests were shown to not be sufficiently reliable and that the same test does not apply to plaintiff's evidence to rebut the claim); Smithkline Beecham, 906 F. Supp. at 182-83; S.C. Johnson & Sons. v. Clorox Co., 930 F. Supp. 753, 780 (E.D.N.Y. 1996) (In making this determination, a fact-finder "should consider all relevant circumstances, including the state of the testing art, the existence and feasibility of superior procedures, the objectivity and skill of the persons conducting the tests, the accuracy of their reports, and the results of other pertinent tests").

Furthermore, Bracco asserts that the FDA's explicit rejection of GEH's claims and the NEPHRIC study as reliable (on at least two occasions), is highly persuasive evidence entitled to significant deference regarding the falsity of GEH's claims. See, e.g., Zeneca, 1999 WL 509471, at *3; Rhone-Poulenc Rorer Pharms. v. Marion Merrell Dow, No. 93-0144, 1994 U.S.Dist. LEXIS 20782, at *13 (W.D. Mo. Sept. 30, 1994), aff'd in part, rev'd in part on other grounds, 93 F.3d 511 (8th Cir. 1996). (See Pl.'s COL ¶ 12). In Zeneca, the court extensively commented on the significance of a published peer reviewed article accompanied by expert testimony as to the validity of its conclusions. 1999 WL 509471, at *27-30. There, the court determined that when the FDA

did not approve of the claim asserted in a peer reviewed article that the underlying article did not constitute a reliable means for disseminating those claims through advertising. Id. Here, the Court finds that the FDA's rejection of the claim that Visipaque performs better renally than all LOCM is persuasive in determining whether false advertising has occurred. While the FDA's determination of reliability and actionable conduct is different than that promulgated under the Lanham Act, it is compelling evidence that the underlying article cannot support a claim that Visipaque performs better renally than all LOCM.

3. GEH's Renal, Cardiovascular, Discomfort-type and Class and Cost Claims for Visipaque and Omnipaque Are Literally False Because GEH's Ads Omit Critical Information That Goes Toward Limitations of its Overly Broad Claims

Moreover, Bracco contends that GEH's renal, cardiovascular, discomfort-type and class and cost claims for Visipaque and Omnipaque all omit critical test results and data that demonstrate limitations of the data. (Pl.'s FOF ¶¶10-17,23-39). Bracco asserts that because such claims are based on selective and unreliable data, while ignoring relevant, contradictory data, they are literally false establishment claims. See, e.g., SmithKline Beecham Consumer Healthcare v. Johnson & Johnson-Merck Consumer Pharma, No. 01-2775, 2001 WL 588846, at *13 (S.D.N.Y. June 1, 2001); E.R. Squibb & Sons Inc. v. Stuart Pharm., No. 90-1178, 1990 WL 159909, at *18 (D.N.J. Oct. 16, 1990) (finding material omission in selective reporting of study's results regarding competitor medication rendered ad literally false); Phillip Morris. v. Loew's Theatres, 511 F. Supp. 855, 856-57 (S.D.N.Y. 1980) (holding that incomplete citation to study data to make own product appear superior rendered advertisement false on its face).

In this Opinion, the Court has found that there is limited or no support for certain of GEH's non-renal claims that (a) Visipaque causes lower incidence of MACE than LOCM; (b) Visipaque causes less discomfort (i.e., claiming less pain, warmth, discomfort or patient movement or designed for such) than LOCM; and (c) Visipaque performs better than LOCM because of lower osmosality and associated costs. With regard to cardiovascular superiority, the Court concludes that there is sufficient support in the VICC trial to support the claim that Visipaque causes less MACE than Isovue for patients undergoing PCI within the initial 48 hours after the procedure, however there is insufficient support in the proffered studies to make a claim that Visipaque has superior hemodynamic effects over LOCM. As to discomfort, the Court finds that GEH's claims of Visipaque comfort superiority to LOCM are supported, but only as to peripheral angiography procedures, and thus, GEH's broad assertions of superior patient comfort are not supported by the conclusions of the various studies it uses to bolster them; any such advertising must be limited to the procedures and circumstances that were used in the studies. Finally, as to a cost superiority claim, the only support for such a claim is to associate the cost of treating additional instances of MACE and CIN to higher overall cost; since the Court has not made such a finding with regard to CIN, the only viable means of advertising lower cost is through less incidence of MACE in the circumstances defined herein.

d. Implied Falsity

Bracco contends, in the alternative, that even if the Court determines that GEH's representations regarding the renal and non-renal superiority of Visipaque are literally true that the representations are still false by implication (e.g., "Visipaque is better than a LOCM", which implies that it is better than Isovue). "Where a plaintiff cannot show that a claim is literally false under the Lanham Act, it must show that the advertisement conveyed an impliedly false message that was

misleading to consumers." AstraZeneca, 444 F. Supp. 2d at 295 (citing Johnson & Johnson-Merck Consumer Pharma. Co. v. Rhone-Poulenc Rorer Pharma., Inc., 19 F.3d 125, 129 (3d Cir.1994)). The Third Circuit has held an "impliedly false message" cannot be proved without considering proof of customer reaction. In Sandoz, the Third Circuit stated that

> where the advertisements are not literally false, see PPX Enterprises v. Audio Fidelity Enterprises, 818 F.2d 266, 272 (2d Cir.1987), plaintiff bears the burden of proving actual deception by a preponderance of the evidence. Hence, it cannot obtain relief by arguing how consumers *could* react; it must show how consumers *actually do* react.

Sandoz, 902 F.2d at 229-30; see, e.g., Novartis, 290 F.3d at 586-87; AstraZeneca, 444 F. Supp. 2d at 295; see also Merck Consumers Pharms, 960 F.2d at 297 ("It is not for the judge to determine, based solely upon his or her own intuitive reaction, whether the advertisement is deceptive. . . [since] the question in such cases is what does the person to whom the advertisement is addressed find to be the message?"). Moreover, context is highly important in discerning the message conveyed, particularly when "the target of the advertising is not the consuming public but a more well informed and sophisticated audience." Sandoz, 902 F.2d at 229. Doctors are sophisticated, knowledgeable consumers who are not easily misled; in contrast to literal falsity claims, in implied falsity claims, this factor must be taken into account for the Court's analysis of whether the message was impliedly false or misleading to the target audience. See, e.g., Id. at 229-30. Likewise, committee members responsible for purchasing decisions who have knowledge of, and experience with, the advertised products are not likely to be deceived. See, e.g., Labware v. Thermo Labsystems, No. 04-2545, 2005 U.S. Dist. LEXIS 12993, at *30-32 (E.D. Pa. June 28, 2005).

In addition, even if the claims were not literally false, Bracco alleges that they are still misleading, as shown by: (a) the Rappeport survey; Merisant Co. v. McNeil Nutritionals, LLC, 515

F. Supp. 2d 509, 526 (E.D. Pa. 2007) (15-20% deception is enough); see also Stiffel Co., 658 F. Supp. at 1114; or (b) GEH's willfulness and intent to deceive (see, e.g., McNeil-P.P.C., Inc. v. Pfizer, Inc., 351 F. Supp. 2d 226, 249 (S.D.N.Y. 2005)). However, in this case, the Court has excluded Rappeport's survey for unreliability and determines that there is no willful conduct; consequently, without survey evidence this Court cannot find that GEH's renal and non-renal claims were impliedly false. Nevertheless, since the Court has already found that certain of GEH's claims are literally false, Bracco need not show customer deception for those specific claims.[254]

4. Actual Deception or at Least a Tendency to Deceive a Substantial Portion of the Intended Audience

a. Presumption of Deception

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[254]GEH makes additional arguments that Bracco has failed to identify the allegedly "misleading" nature of any accused advertisement with specificity in its survey and that it has also failed to present evidence of "actual deception" through a valid survey. As set forth above, Dr. Rappeport's survey, which tested two statements that purportedly appeared on select web pages from the multi-page website www.visipaque.com, was not conducted in accordance with accepted principles of survey research. AstraZeneca, 444 F. Supp. 2d at 291-293; Church & Dwight Co. v. S.C. Johnson & Son, Inc., 873 F. Supp. 893, 906-11 (D.N.J. 1994); Am. Home Prods., 871 F. Supp. at 761-62; Smithkline Beecham, 960 F.2d at 300-01; Procter & Gamble, 2006 WL 2588002, at *25, 27 (excluding survey of doctors for failure to include a control group).

In addition, GEH correctly argues that even if credited, which the Court has declined to do here, those results cannot be applied to: (i) statements not tested, or (ii) statements in media other than those surveyed. AstraZeneca, 444 F. Supp. 2d at 296 (television survey not applied to print ad, website materials, or pamphlets); Am. Home Prods., 871 F. Supp. at 750 (refusing to extend a survey on a television ad and an insert to other print ads, even though they contained elements in common with the messages tested). Further, the survey tested only statements from foreign websites. Bracco has offered no survey evidence of actual deception from, for example., any accused print ads or sales rep statements. It also has not shown actual deception from any statements that were not tested in surveys, including those regarding cardiac events or Visipaque being iso-osmolar. See e.g., AstraZeneca, 444 F. Supp. 2d at 296 n.12. Mr. Russell's opinions regarding GEH's marketing "messages" and his assumptions about their effect cannot substitute for a valid consumer survey, hence, once again Bracco's claim of impliedly misleading messages fails.

Many courts, including the Third Circuit, impose a rebuttable presumption of customer deception when there is a finding of literal false advertising. See, e.g., Castrol, 987 F.2d at, 943 (confirming that in the Third Circuit, where the advertisement is shown to be literally false, the court may enjoin it without reference to its impact on the consumer); Cashmere & Camel Hair Manuf. Institute v. Saks Fifth Ave., 284 F.3d 302, 314-16 (1st Cir. 2002) ("it has become the practice of most circuits to apply the [customer deception] presumption to all literal falsity claims"); PPX Enters., 818 F.2d at 272-273; EFCO Corp. v. Symons Corp., 219 F.3d 734, 740 (8th Cir. 2000); Solvay Pharm. Inc. v. Global Pharm. Inc., 419 F. Supp. 2d 1133, 1144-45 (D. Minn. 2006); Iams Co. v. Nutro Prods. Inc., No. 00-566, 2004 U.S. Dist. LEXIS 15134, at *13-14 (S.D. Ohio July 3, 2004). In addition, courts will also presume customer deception where defendant's misconduct is willful and egregious. See, e.g., Cashmere, 284 F.3d at 316; Columbus Rose Ltd. v. New Millennium Press, No. 02-2634, 2002 WL 1033560, *7 (S.D.N.Y. May 20, 2002).

b. Dissemination of Allegedly False Message to Substantial Portion of the Intended Audience

GEH's sales call records are admissible as business records, as GEH has agreed, and are highly probative of what GEH's sales representatives communicated. While some of the records are fragments of communications, based on their content, the records show that the sales representatives disseminated both false renal and non-renal claims. Bracco relies on Mr. Russell's expert testimony that at least 87% of GEH representatives documented delivery of false and/or misleading messages and at least 82.5% of substantive calls overall are "on message." As discussed supra, the Court found these percentages to be grossly inflated. Nonetheless, GEH did disseminate false renal and non-renal messages to the market. Customers were exposed to the claims through various channels

(e.g., sales representatives, meetings, CME's, press releases, and websites). The claims from the different sources, when examined as part of the entire campaign, further demonstrate that GEH had a widespread campaign to promote Visipaque, with some of the ads containing false claims. See, e.g., McNeil-P.C.C., 938 F.2d at 1546.

Therefore, the evidence of GEH's sales and marketing efforts demonstrates that GEH management used market research and experience to craft the claims that would have the most impact on customers (Pl.'s FOF ¶ 4), told the sales representatives to disseminate the claims (Pl.'s FOF ¶ 5), the sales representatives disseminated the claims, as recorded in print ads, sales call records, emails and other records (Pl.'s FOF ¶¶ 6-9,18-22), and that some of these claims were false. GEH's print media and CME-type presentations also disseminated its false claims.

5. The Accused Materials Were Material in That They Were Likely to Influence Purchasing Decisions

Bracco maintains that there is overwhelming evidence (e.g., Pl.'s FOF ¶ 42), that GEH's false and misleading claims of superior safety are material to customers. "The materiality inquiry 'focuses on whether the false or misleading statement is likely to make a difference to purchasers.'" Labware v. Thermo Labsystems, Inc., No. 04-2545, 2005 U.S. Dist. LEXIS 12993, at *31-35 (E.D. Pa. Jun. 28, 2005) (quoting Cashmere, 284 F.3d at 312 n.10 (citing J. Thomas Mccarthy, Mccarthy on Trademarks and Unfair Competition § 27:35 (4th ed. 2001)). "Once it is determined that a statement is false, it is presumed to be material." Telebrands Corp. v. E. Mishan & Sons, No. 97-1414, 1997 WL 232595, at *22 (S.D.N.Y. May 7, 1997).

> The type of evidence needed to prove materiality . . . varies depending on what type of recovery the plaintiff seeks. Plaintiffs looking to recover monetary damages for false or misleading advertising that is not literally false must prove actual deception. See Balance Dynamics Corp. v. Schmitt Ind., 204 F.3d 683, 690 (6th Cir.2000);

> [Resource Developers, Inc., v. Statute of Liberty-Ellis Island Foundation, Inc., 926 F.2d 134, 139 (2d Cir. 1991)]. Plaintiffs attempting to prove actual deception have to produce evidence of actual consumer reaction to the challenged advertising or surveys showing that a substantial number of consumers were actually misled by the advertisements. See, e.g., PPX Enters., Inc. v. Audiofidelity Enters., Inc., 818 F.2d 266, 271 (2d Cir.1987) ("Actual consumer confusion often is demonstrated through the use of direct evidence, e.g., testimony from members of the buying public, as well as through circumstantial evidence, e.g., consumer surveys or consumer reaction tests.")
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> . . . .
>
> Plaintiffs seeking injunctive relief must prove that defendant's representations "have a tendency to deceive consumers." Balance Dynamics, 204 F.3d 683 at 690; see also Resource Developers, 926 F.2d at 139; Blue Dane Simmental Corp. v. American Simmental Assoc., 178 F.3d 1035, 1042-43 (8th Cir.1999); Black Hills Jewelry Mfg. Co. v. Gold Rush, Inc., 633 F.2d 746, 753 (8th Cir.1980); 4 McCarty on Trademark and Unfair Competition § 27:36 (4th ed.)

Pizza Hut, Inc. v. Papa John's Int'l, Inc., 227 F.3d 489, 497 (5th Cir. 2000). In this case, as discussed supra, the Court finds that GEH disseminated literally false statements, and GEH has not provided a sufficient defense to rebut a finding of deception or materiality. Thus, given these findings, it is not necessary to inquire into the impact on the customer; the Court finds that GEH's representations to the public were material. Bracco, in addition to seeking injunctive relief, seeks monetary damages; however, the Court notes that although the presumption of materiality, as it applies when there is a finding of literal falsity, is highly relevant to injunctive relief, the Court needs to make additional findings before imposing an award of damages, which will be discussed below.

6. Injunctive Relief

Under the Lanham Act, an injunction is a "usual and standard remedy" and "the common historical practice has been that a prevailing plaintiff in a case of . . . false advertising will ordinarily receive injunctive relief of some kind." 5 J. Thomas McCarthy, Trademarks & Unfair Competition

§ 30:1 (4th ed. 2006); Lermer Germany GmbH v. Lermer Corp., 94 F.3d 1575, 1577 (Fed. Cir. 1996).

> In deciding whether to grant a permanent injunction, the district court must consider whether: (1) the moving party has shown actual success on the merits; (2) the moving party will be irreparably injured by the denial of injunctive relief; (3) the granting of the permanent injunction will result in even greater harm to the defendant; and (4) the injunction would be in the public interest.

Gucci America, Inc. v. Daffy's Inc., 354 F.3d 229, 236-37 (3d Cir. 2003) (quoting Shields v. Zuccarini, 254 F.3d 476, 482 (3d Cir.2001)). Trademark case law applies to the remedies sought in this action: Congress amended the Lanham Act to expressly make all trademark remedies available in false advertising cases, (Pub. L. No. 100-667, tit. I § 132, 202 stat. 3935), and numerous courts have since applied trademark precedent to false advertising damages claims. See, e.g., Callaway Golf Co. v. Slazenger, 384 F. Supp. 2d 735, 740-41 (D. Del. 2005); Castrol, Inc., 169 F. Supp. 2d at, 344.

Here, the Court is the fact-finder , and has found that GEH's conduct is in violation of the Lanham Act; accordingly, Bracco has demonstrated actual success of the merits and in turn, irreparable injury. (Pl.'s FOF ¶ 88); Citizens Fin. Group, 383 F.3d at125 (trademark infringement amounts to irreparable injury as a matter of law). With respect to the third factor, the Court has fashioned a remedy that permits GEH to use advertisements that market Visipaque in a manner that does not run afoul of the Lanham Act. Finally, it is well within the public interest for this Court to enjoin GEH from disseminating false messages regarding Visipaque. Abbott, 971 F.2d at 19. Accordingly, Bracco is entitled to the appropriate injunctive relief as set forth in this Opinion (i.e. - how GEH can advertise its renal and non-renal claims in the future without being exposed to Lanham Act liability and what types of statements would constitute false advertising).

Also, as far as corrective action, the Court orders the following: GEH to issue a press release, including on its website, regarding this Court's decision and the placement of corrective ads. Corrective advertising is appropriate when, as here, a defendant is making false claims about its product that bear on the public health. See, e.g., Abbott, 971 F.2d at 19 (citing Wojnarowicz v. American Family Ass'n, 745 F. Supp. 130, 141 (S.D.N.Y. 1990)); Johnson & Johnson Vision Care, Inc. v. Ciba Vision Corp., 348 F. Supp. 2d 165, 185 (S.D.N.Y. 2004). The Court also orders GEH to re-train its sales and marketing personnel in accordance with this opinion. See Zeneca, 1999 WL 509471, at *42 ("The Court hereby orders defendant Eli Lilly to design and implement a training program . . ."); Pfizer, Inc. v. Miles, Inc., 868 F. Supp. at 461; Marion Merrell Dow, 93 F.3d at 516. The Court also orders that to the extent that there is any dispute between Bracco and GEH arising from GEH's future advertising that may run afoul of this Court's Opinion, those disputes shall be submitted to a neutral panel or individual of the parties' choice, such as the National Advertising Division ("NAD"), a division of the Council of Better Business Bureau, for resolution.[255] In that connection, GEH shall bear the costs associated with submitting these disputes, if the ads are found to be false. However, in the event that the panel or individual finds that the advertisements are not false, Bracco shall be responsible for the costs.

7. Damages under the Lanham Act

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[255]On its website, NAD describes itself as a low-cost alternative to litigation, providing companies with a forum to air their disputes over the veracity of national advertisements. "NAD uses a unique, hybrid form of alternative dispute resolution, working closely with in-house counsel, marketing executives, research and development departments and outside consultants to decide whether claims have been substantiated. Each party to the dispute has ample opportunity to explain its position and provide supporting data." About NAD, www.nadreview.org/AboutNAD.aspx.

Having already determined that an injunction is appropriate in this case, the Court next decides whether monetary damages should be awarded; § 35(a) of the Lanham Act provides that the plaintiff shall be entitled to recover damages in an action

> subject to the principles of equity, [including] (1) defendant's profits, (2) any damages sustained by the plaintiff, and (3) the costs of the action. The court shall assess such profits and damages or cause the same to be assessed under its direction. In assessing profits the plaintiff shall be required to prove defendant's sales only; defendant must prove all elements of cost or deduction claimed. In assessing damages the court may enter judgment, according to the circumstances of the case, for any sum above the amount found as actual damages, not exceeding three times such amount. If the court shall find that the amount of the recovery based on profits is either inadequate or excessive the court may in its discretion enter judgment for such sum as the court shall find to be just, according to the circumstances of the case. Such sum in either of the above circumstances shall constitute compensation and not a penalty. The court in exceptional cases may award reasonable attorney fees to the prevailing party.

15 U.S.C. § 1117(a). District courts have broad discretion to fashion monetary relief under § 35(a). See, e.g., Banjo Buddies, Inc. v. Renofsky, 399 F.3d 168, 176 (3d Cir. 2005); Gilson § 14.03[2]; see also Callmann § 23:56.

In Lanham Act cases, the causation standard for an award of damages is higher than the general standard for injunctive relief:

> [C]ases involving injunctive relief and those seeking monetary damages under the Lanham Act have different standards of proof. A plaintiff suing to enjoin conduct that violates the Lanham Act need not prove specific damage. In contrast, courts require a heightened level of proof of injury in order to recover money damages.

Porous Media Corp. v. Pall Corp., 110 F.3d 1329, 1335 (8th Cir. 1997); see also Parkway Baking v. Freihofer Baking, 255 F.2d 641, 648-49 (3d Cir. 1958). Thus, a plaintiff seeking monetary rather than injunctive relief must show "actual damages rather than a mere tendency to be damaged." Syngy v. Scott-Levin, 51 F. Supp. 2d 570, 575 (E.D. Pa. 1999). Moreover, a plaintiff seeking

monetary damages must show more than a mere presumption of actual customer confusion based on a finding of literal falsity. See Societe Civile Succession Richard Guino v. Beseder Inc., No. 03-1310, 2007 U.S. Dist. LEXIS 83782, at *19-20 (D. Ariz. Oct. 31, 2007) ("While a finding of literal falsity does support a presumption of actual confusion among consumers, this presumption does not somehow demonstrate that [the Lanham Act plaintiff] was damaged by such confusion in this case."); see also Porous Media, 110 F.3d at, 1335-36 ("A plaintiff suing to enjoin conduct that violates the Lanham Act need not prove specific damage . . . [however] [i]n contrast, courts require a heightened level of proof of injury in order to recover money damages"). The plaintiff must link the deception with actual harm to its business. Id. "Actual damages cannot exist without a nexus between a false advertisement and an adverse purchasing decision." Labware, 2005 U.S. Dist. LEXIS 12993 at 36 (citing Syngy, 51 F. Supp. 2d at 577 and IQ Prods., 305 F.3d at 376).

An advertisement or promotion is harmful if there is a likelihood of injury to the plaintiff in the form of declining sales, loss of good will, and the like. Warner-Lambert, 204 F.3d at 91-92; see, e.g., U.S. Healthcare Inc., 898 F.2d at 922-23; Warner-Lambert Co., 204 F.3d at 92; GlaxoSmithKline, 197 Fed. Appx. at 123. For example, a "predicate finding of intentional [or willful] deception, as a major part of the defendant's marketing efforts, contained in comparative advertising[;]" will justify a rebuttable presumption of causation and injury in fact. Porous Media, 110 F.3d at 1335-36; see, e.g., Balance Dynamics, 204 F.3d at 694-95 (applying Porous Media but finding presumption rebutted); HipSaver Co. v. J.T. Posey Co., 497 F. Supp. 2d 96, 106 (D. Mass 2007) (holding that weight of First Circuit authority supported rebuttable presumption of causation and injury for willful, literally false comparative advertising in two-player market); Ott A.G. v. Target Corp., 153 F. Supp. 2d 1055, 1073-74 (D. Minn. 2001) (recognizing presumption of causation

and injury for comparative, deliberately deceptive advertising); see also McCarthy § 30:63, § 27:42 ("courts in some situations will make a monetary award in the absence of direct proof of actual confusion where defendant is a willful infringer. . . . [W]here confusion of customers was intended by defendant, actual confusion will be presumed to have occurred, and the burden is on defendant to prove otherwise"); Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1146 (9th Cir. 1997) ("inability to show actual damages does not alone preclude a [monetary] recovery").

Other courts have noted that, in limited circumstances, literally false advertising, by raising a presumption of consumer deception, may support a finding of a causal nexus between defendant's misconduct and plaintiff's injuries. See, e.g., EFCO Corp. v. Symons Corp., 219 F.3d 734, 740 (8th Cir. 2000) (literal falsity of ads, plaintiff's lost revenues coupled with defendant's increased revenues, and plaintiff's loss of clients was "sufficient causal nexus"); Cashmere, 284 F.3d at 319 (finding causal link based on literal falsity and the "common sense" inference that "sale of cashmere-blend coats which overstated their cashmere content could cause a loss of sales of cashmere-blend coats which correctly state their cashmere content"); Iams Co., 2004 U.S. Dist. LEXIS 15134 at *13-14 (where advertising is literally false and comparative and "competitor's products are specifically targeted, a plaintiff is also entitled to a presumption of money damages"); Gilson, § 14.03[3][b] ("in advertising cases, courts are willing to grant monetary relief absent evidence of actual deception based on widely accepted presumptions."). However, case law makes clear that "literal falsity, without more, is insufficient to support an award of money damages to compensate for marketplace injury." Balance Dynamics, 204 F.3d at 694-95; BASF Corp. v. Old World Trading Co., 41 F.3d at 1085-88 (finding literal falsity but requiring further proof of marketplace damages); Castrol, 987 F.2d at 941-43(affirming trial court decision granting injunctive

relief but denying monetary damages despite finding of literal falsity). Societe Civile, 2007 U.S. Dist. LEXIS 83782 at *19-20 ("While a finding of literal falsity does support a presumption of actual confusion among consumers, this presumption does not somehow demonstrate that [the Lanham Act plaintiff] was damaged by such confusion in this case"). Accordingly, in order for the Court to grant monetary relief, it must find either (1) that GEH engaged in willful conduct; or (2) that GEH's false advertising, while not willful, was a material factor in causing Bracco's lost profits. (Pl.'s FOF ¶¶ 43 - 82, 84, 95, n. 97.) These are the inquires to which the Court shall turn.

a. Willfulness

Bracco must first establish willfulness before entitlement to a presumption of causation and harm. See Castrol Inc., 169 F. Supp. 2d at 341.[256]

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[256] GEH contends that Bracco must present clear and convincing evidence in order for this Court to find willfulness. In support, GEH relies on several cases. Castrol Inc., 169 F. Supp. 2d at 341 (requiring a showing of clear and convincing evidence that the defendant's false advertising was willful); Versa Prods. v. Bifold Co., 50 F.3d 189, 208 (3d Cir. 1995) (applying clear and convincing standard to prove willfulness of trade dress infringement); Tamko Roofing Prods. v. Ideal Roofing Co., 294 F.3d 227, 229 (1st Cir. 2002) (applying the clear and convincing evidentiary standard to establish willfulness in trademark infringement action). Similarly, the Court notes that in other contexts a heightened standard may apply, such as requiring a prevailing party seeking attorneys' fees under § 1117(a) to demonstrate the exceptional nature of a case by clear and convincing evidence, see e.g., Schlotsky's Ltd. v. Sterling Purchasing Nat. Distribution Co., Inc., 520 F.3d 393, 402 (5th Cir. 2008); see also Seven-Up, 86 F.3d at 1390 (finding that under 15 U.S.C. § 1117(a), an "exceptional case" is one in which the infringing party acted maliciously, fraudulently, or wilfully); and to establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent. In re Seagate Tech., LLC, 497 F.3d 1360, 1371 (Fed. Cir. 2007). By contrast, a district court in Oregon recently declined to apply a clear and convincing standard to the plaintiff's willfulness showing in support of its claim of lost profits. Adidas Am., Inc. v. Payless Shoesource, Inc., No. 01-1655, 2008 U.S. Dist. LEXIS 69260, at *25-26 (D. Or. Sept. 12, 2008). In Adidas, the court relied on Gracie v. Gracie, 217 F.3d 1060, 1068-69 (9th Cir. 2000), which held that a jury charge on willfulness did not need to instruct the jury that it must find willfulness by a clear and convincing standard. However, the Court is not persuaded by Adidas. Specifically, the Adidas court reasoned that the Ninth Circuit requires a plaintiff seeking lost profits to demonstrate that the defendant acted wilfully. Id. ("A

> In the context of a false advertising claim under the Lanham Act, " 'willfulness' and 'bad faith' require a connection between a defendant's awareness of its competitors and its actions at those competitors' expense." ALPO Petfoods, Inc. v. Ralston Purina Co., 913 F.2d 958, 966 (D.C.Cir.1990). "Voluntary, knowing and intentional misconduct" is considered an indicator of willfulness. See Castrol Inc., 169 F. Supp.2d at 341.

Callaway, 384 F. Supp. 2d at 742. Recently, the Supreme Court in Safeco Ins. Co. of America v. Charles Burr, 127 S. Ct. 2201 (2007), held that: "[W]illfully is a word of many meanings whose construction is often dependent on the context in which it appears, and where willfulness is a statutory condition of civil liability, we have generally taken it to cover not only knowing violations of a standard, but reckless ones as well." Id. at 2208 (citations and quotations omitted) (emphasis added). The Supreme Court also found that: "[T]he term recklessness is not self-defining, [but] the common law has generally understood it in the sphere of civil liability as conduct violating an objective standard: action entailing an unjustifiably high risk of harm that is either known or so obvious that it should be known." Id. at 2215 (citations and quotations omitted). While Safeco's holding is not in the context of false advertising, the court in Lorillard Tobacco Co. v. Yazan's Serv. Plaza, Inc., No. 05-70804, 2007 U.S. Dist. LEXIS 45612, at *14-15 (E.D. Mich. Jun. 25, 2007), applied Safeco's definition of reckless conduct to find willfulness. The Court finds Lorillard's reasoning sound and persuasive, particularly in light of the Supreme Court's guidance. As such, a finding of recklessness, or voluntary and intentional conduct will suffice to demonstrate wilfulness.

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defendant's profits can only be disgorged to prevent unjust enrichment if the trademark infringement was willful.") (citation omitted). The Third Circuit, however, has rejected a bright-line wilfulness requirement, instead considering a demonstration of willfulness as an important, but not dispositive, factor in the lost profits analysis. Banjo Buddies, 399 F.3d at 176-77. Nevertheless, the Court need not resolve the apparent tension in the law because Bracco has presented scant evidence to establish that GEH's false advertising was done willfully.

In this case, Bracco implores the Court to find that GEH's commission of false advertising (Pl.'s FOF ¶¶ 83-87) is willful, thus creating a rebuttable presumption of causation and harm. Albeit the Court finds that some accused claims were false or misleading, the Court does not find that GEH's actions rise to the level of willfulness. Particularly, in Callaway, cited by Bracco, the court found willful conduct when the defendant continued to disseminate ads with claims of superiority of its golf ball product line over all other competitor golf ball product lines on tour, when its own tests showed that a competitor's golf ball product line on tour was superior. 384 F. Supp. 2d at 742. However, in this case, there are studies and knowledgeable and credible experts supporting the challenged statements, as well as legitimate questions regarding the validity of the studies relied upon by Bracco. See Castrol Inc. v. Penzoil Inc., 799 F. Supp. 424, 441 (D.N.J. 1992) (where the court rejected the defendant's expert testimony as unconvincing, nonetheless it found that it was a worthy effort which dispelled any judicial consideration of bad faith, malice, fraud, or willfulness).

Also convincing is GEH's reliance on its inter-department approval process for promotional materials. Specifically, as discussed supra p. 59, GEH identified four levels of internal mechanisms that reviewed prospective promotional materials to ensure consistency with clinical data. Although this Court finds some of the messages approved by this process are literally false, the fact that these materials were subject to extensive review militates against a finding of willfulness. Indeed, Mr. Scott Kerachsky, Director of Marketing for GEH Healthcare, testified that when reviewing prospective promotional materials with respect to NEPHRIC from the marketing department's prospective, he considered possible issues with the FDA and clarified wording of the materials in light of the clinical conclusions in NEPHRIC. Bracco does not contest the validity of this approval process, i.e. there is no allegation that the process is a sham. Such a detailed process tends to show

that GEH was not reckless or careless in its approval of the offending messages. Thus, the Court finds GEH's internal review process of the promotional materials probative in finding that GEH's conduct was not willful.

In addition, in contrast to the clearly willful conduct in Callaway, here there were no studies that adequately and reliably demonstrated a LOCM's superiority over Visipaque. Rather, there were studies supporting a particular claim of Visipaque superiority over at least a LOCM (e.g. - Omnipaque, Hexabrix, and in VICC, Isovue). Simply put, Bracco has failed to present sufficient evidence to prove that GEH's actions were willful. As such, the Court has no basis to find that GEH knowingly or willfully disseminated false or misleading information.

In finding that GEH's conduct was not willful, the Court notes that Bracco may still be entitled to disgorgement of GEH's profits if it can satisfy the other five factors set forth in Banjo Buddies. For disgorgement of profits, a plaintiff has the burden of proving that such a remedy is warranted. Castrol Inc., 169 F. Supp. 2d at 341 n.8; CollegeNET, Inc. v. XAP Corp., 483 F. Supp. 2d 1058, 1061 (D. Or. 2007). Disgorgement may be awarded based on three distinct rationales: (1) deterrence; (2) unjust enrichment; and (3) compensation for actual damages. Banjo Buddies, Inc., 399 F.3d at 177-178. The plaintiff bears the burden of showing that the sales for which it seeks disgorgement occurred because of the alleged false advertising. See Gucci, 354 F.3d at 242 n.15; Castrol Inc., 169 F. Supp. 2d at 343 ("Surely, Castrol must demonstrate with reasonable certainty the portion of Pennzoil's profits attributable to the willful and intentional false advertising before the Court can order disgorgement."); Logan v. Burgers Ozark Country Cured Hams, 263 F.3d 447, 464-65 (5th Cir. 2001); Balance Dynamics, 204 F.3d at 695.

The Third Circuit weighs five non-exclusive factors in determining a Lanham Act plaintiff's entitlement to disgorgement: "(1) whether the defendant had the intent to confuse or deceive; (2) whether sales have been diverted; (3) the adequacy of other remedies (such as injunctive relief or compensatory damages); (4) any unreasonable delay by the plaintiff in asserting its rights; and (5) the public interest in making the misconduct unprofitable."[257] Banjo Buddies, 399 F.3d at 175; Merisant, 515 F. Supp. 2d at 529 (applying Banjo Buddies in the false advertising context). The plaintiff is not required to prove all factors; rather, they are weighed to determine whether the balance tips in favor of disgorgement. Pebble Beach Co. v. Tour, 181, 155 F.3d 526, 554 (5th Cir. 1998).

In weighing Banjo Buddies' five relevant factors for determining whether disgorgement is appropriate, the Court here finds an award of disgorgement inequitable. First, GEH's actions were not willful or deliberate - the creation of confusion and deception among customers due to GEH's advertising campaign was based on scientific studies and articles that had limited applicability, and furthermore, no scientific studies have explicitly found the converse of GEH's advertisements.[258] (see Pl.'s FOF ¶¶ 42,83-87). This finding strongly militates against an award of profits. See Banjo Buddies, 399 F.3d at 175 As to the second factor, the Court finds that sales were not diverted from Bracco to GEH as a result of GEH's false advertising. See supra, pp. 56-76. Indeed, the evidence does not show that certain sales and awards of GPOs, including Consorta, Novation, and Kaiser,

[257] A sixth factor, "palming off," applies to trademark actions, but is not applicable to false advertising actions.

[258] The NEHPRIC Article was published in a very highly acclaimed medical journal, making an even stronger case that GEH's actions were reasonable at the time and not carried out in a willful manner.

caused profits that resulted from GEH's false advertising. See Id. Rather, the totality of evidence tends to show that the GPO contracts were not awarded as a result of false advertising, but for other reasons, including, but not limited to, client satisfaction with GEH's products, longstanding business relationships with GEH, dissatisfaction with certain of Bracco's productline (ProHance), Bracco's pricing and approach to the bid process, and Visipaque's distinction as an innovative product.

As to the third factor, the Court concludes that other remedies, i.e., injunctive relief and compensatory damages for past and future advertising costs on Bracco's behalf to clarify the advertising claims, are adequate and can make the Plaintiff in this case whole without the exceptional remedy of disgorgement. Fourth, Bracco did not delay in asserting its rights; it responded to GEH's 2003 campaign immediately by contacting GEH and the FDA, and filed suit soon thereafter (December 2003). Finally, while strong public policies exist to make false advertising unprofitable, deter false statements about drug safety, encourage disclosure of drug safety data, and deter inflated drug prices based on false clinical claims, in this case, the Court finds that deterrence alone is not a supportable rationale for disgorgement, especially in light of the fact that GEH's violative conduct is not willful. See Tamko Roofing, 282 F.3d at 38 ("In cases of at least some direct competition and willfulness, some role may exist for deterrence in an award of an

accounting of profits").[259] [260] [261] Although there may be some deterrence value for GEH and the general marketplace, the Court finds that it is insufficient, when weighing all the other factors, to merit disgorgement.

b. Bracco's Lost Profits on the GPO Contracts

Absent a presumption of causation, under § 35(a)(2) Bracco is entitled to damages for its lost profits only if it shows that GEH's misconduct was a material factor (also called a "substantial" factor) in Bracco's losses. "In order to prove causation under. . .the Lanham Act, the aggrieved party

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[259]In addition, the Court notes that the Lanham Act does not provide for trebling of disgorgement of defendant's profits, but that a court may adjust an award of defendant's profits either upward or downward, in the interest of equity, provided any award does not exceed more than three times the amount of actual damages. 15 U.S.C. § 1117(a); Donsco, 587 F.2d at 607-08. However, here the court has held that disgorgement is not an appropriate remedy, let alone considered enhancment of it. Such a result would constitute a windfall to Bracco. Thus, even if Bracco were entitled to disgorgement of profits, which it is not, the Court would not increase any such award in the interest of equity.

[260]The Court notes that numerous courts have adopted an "Account Specific" approach to calculate damages. See, e.g., Sweetzel, Inc. v. Hawk Hill Cookies, Inc., No. 95-2632, 1996 U.S. Dist. LEXIS 8562, at *9 (E.D. Pa. June 19, 1996). Courts have also relied on a "Sales Trend" approach for damages. Procter & Gamble Co. v. Paragon Trade Brands, Inc., 989 F. Supp. 547 (D. Del. 1997); McCarthy § 30:79. Bracco's damages expert, Mr. Malackowski, applied both a "Account Specific" approach and a "Sales Trend" approach. However, since the Court has not found that disgorgement is appropriate in this case, it does not reach the inquiry of which method is most proper for the calculation of disgorgement damages.

[261]Bracco also asserts that disgorgement need not account for third party competitors. Bracco relies on authority which holds that when multiple competitors compete for sales in the market, it is acceptable to disgorge all of a defendant's increased profits without accounting for the presence of third party competitors. Callaway, 384 F. Supp. 2d at 743; Tamko Roofing, 282 F.3d at 34; Banjo Buddies, 399 F.3d at 177 (3d Cir. 2005). Although the record supports that the market, outside of the Premier GPO, effectively is split between GEH and Bracco, who also were the primary competitors for all accounts specifically at issue (e.g., Novation, Consorta, Kaiser), (Pl.'s FOF ¶¶ 51,59,72), it is not necessary for the Court to reach this question either, as disgorgement is not being ordered.

must demonstrate that the false advertisement actually harmed its business." Cashmere, 284 F.3d at 318; see Xoom, Inc. v. Imageline, Inc., 323 F.3d 279, 286 (4th Cir. 2003). Numerous courts have applied the material factor test in the false advertising context. See, e.g., Seven-Up, 86 F.3d at 1387 n.12("it is [] necessary that plaintiff demonstrate that defendant's illegal conduct was a substantial cause of injury to plaintiff's business") (quoting American Rockwool, Inc. v. Owens-Corning Fiberglass Corp., 640 F. Supp. 1411, 1444 (E.D.N.C. 1986))(emphasis added); Peerless Heater Co. v. Mestek, Inc., No. 98-6532, 2000 U.S. Dist. LEXIS 6664, at *11 (E.D. Pa. May 12, 2000) ("To satisfy this causation requirement, the plaintiff must prove that the defendants' activities were a material cause of the injury.")(emphasis added); U-Haul Int'l, Inc. v. Jartran, Inc., 601 F. Supp. 1140, 1150 (D. Ariz. 1984); see also R.C. Bigelow, Inc. v. Liberty Mut. Ins. Co., 287 F.3d 242, 248 (2d Cir. 2002); Dan B. Dobbs, The Law of Torts § 171 at 415 (2000); Prosser & Keeton on The Law of Torts § 41, at 266 (5th ed. 1984); Restatement (Second) of Torts §§ 432, 433B (1977).

The Third Circuit has also addressed the analogous issue of whether an "advertising injury" was "caused" by an insured's alleged false advertising:

> Courts that reason that the injury could have taken place without the advertising . . . are misstating the relevant tort liability principles, which ask whether the advertising did in fact contribute materially to the injury.

Travelers, 193 F.3d at 751 n.8 (the court addressed the causation issue at length to resolve "much confusion in the caselaw")(emphasis added).

One way for a plaintiff to prove causation for damages under § 35(a)(2) is to show diversion of customers. Resorts Intern., Inc. v. Greate Bay Hotel and Casino, Inc., 830 F. Supp. 826, 838 (D.N.J. 1992). This "does not place upon the plaintiff a burden of proving detailed individualization of loss of sales" but only "a showing of some customer reliance on the false advertisement." Id.; see

also McCarthy § 27:42 (proof of causation through diverted sales requires only "evidentiary showing of some diverted sales from which more can reasonably be extrapolated") (citing Parkway Baking, 255 F.2d at 641); 1 Robert L. Dunn, Recovery of Damages For Lost Profits § 1.8 (1998) ("Proof of the fact of damages in a lost profits case means proof that there would have been some profits"); Zenith Radio Corp. v. Hazeltine Research, 395 U.S. 100 (1969) (in analogous case of proving causation for antitrust damages, court requires only proof of some damage flowing from violation of the Clayton Act).

Diversion of sales can be proven either through direct or circumstantial evidence. See EFCO, 219 F.3d at 740; BASF, 41 F.3d at 1093-94 (where the court used evidence presented to come up with its own market share analysis of lost damages). Circumstantial evidence may include "consumer surveys, market analysis, or the nature of the defendants' misconduct." Restatement (Third) of Unfair Competition § 36 comments h and i. Although circumstantial evidence illustrating sales trends may suffice in some cases, where "many potential intervening factors can affect the plaintiff's sales, and the presence of such factors bears on the sufficiency of the plaintiff's proof," a sales trend approach will be insufficient to demonstrate causation Id. comment i ("proof of a general decline in sales or a disruption of anticipated business growth following the defendants' misconduct can be sufficient in some cases to justify an inference of causation"). Furthermore, some courts have implied that proof of a sales decline while in direct competition with a defendant may be enough to show causation where the defendant failed to introduce sufficient evidence tending to show other causes for the sales decline. Brunswick v. Spinit Reel, 832 F.2d 513, 525 (10th Cir. 1987) (after finding actual confusion and direct competition between the two parties' products, the court was satisfied that the damages causation nexus was met where all spin-cast reels sales generally dropped

6% because of the recession, but the plaintiff's particular spin-cast reel dropped 16%); EFCO, 219 F.3d at 740 (finding sufficient causation where plaintiff's decline in revenues and defendant's increase in profits were accompanied by evidence that showed plaintiff's lost clients sought out defendant's product).

Bracco first asserts that a causal link also can be shown by a "commonsense" inference that the false statements at issue would damage plaintiff's sales. For example, the First Circuit approved a "district court's commonsense inference that the sale of cashmere-blend coats which overstated their cashmere content could cause a loss of sales of cashmere-blend coats which correctly stated their cashmere content." Cashmere, 284 F.3d at 319 (internal punctuation and citation omitted). However, Bracco fails to acknowledge that the First Circuit cautioned that such an inference would be unreasonable if the defendants could demonstrate that "their garment prices would have remained the same even if they had used Packard fabric." Id.; see also Seven Up, 86 F.3d at 1388. Here, the Court does not find that the evidence gives rise to a commonsense inference; rather, the evidence more convincingly demonstrates that Bracco's loss of sales resulted from a variety of other factors wholly unrelated to GEH's false advertising. See Cashmere, 384 F.3d at 319. Indeed, a commonsense inference in Bracco's favor on the issue of lost profits would be unreasonable given this Court's findings and the evidence presented at trial, which show that GEH's false advertising was not a material or substantial factor in the decision to award the GPO contracts to GEH.

Simply put, Bracco has not met its burden of establishing causation. Indeed, the First Circuit's reasoning in Cashmere follows that of the Fifth Circuit's in Seven-Up, which this Court finds compelling. Specifically, the Fifth Circuit held that proof of an adverse purchasing decision which followed in chronology the alleged false advertising does not prove that the adverse

purchasing decision was a result of the alleged false advertising. Seven-Up, 86 F.3d at 1388. Much like the case at bar, in Seven-Up, the court reasoned that "inferences of causation based solely on the chronology of events, where the record contains undisputed testimony to the contrary or other equally credible theories of causation," are not reasonable inferences. Id. The court ultimately held that a jury could not make a reasonable inference that a presentation containing false advertising was a substantial cause of the plaintiff's loss of a contract to its competitor where there was no evidence as to which specific false slides were presented to the company's Board or to show that the company board actually relied on the information contained in the presentation, much less anything false or misleading therein, Seven-Up, 86 F.3d at 1388-89, particularly where the CEO and Chairman of the Board testified without contradiction that he did not rely on the presentation. The Court finds Seven-Up apposite.

In attempting to prove causation, Bracco has identified several forms of evidence, (emails, expert testimony, and various internal GEH documents), in support of its claim of false advertising. As discussed at length, supra, this Court finds that GEH's false advertising was not a material or substantial factor in the Novation, Consorta, and Kaiser GPO contract awards. Even Bracco's most compelling evidence – emails of conversations with GPO members containing false information and slides presented to GPO members containing false information – does not meet Bracco's burden of showing that it was GEH's false advertising and not the GPOs' independent evaluation of the various scientific studies which caused the loss of the contracts. Although the record shows that Visipaque is considered to be a unique and innovative product throughout the CM industry, this product differentiation does not mean that the view was based on GEH's false advertising; in fact, most of GEH's Visipaque advertising campaign disseminated messages that were not false, and were based

on studies that the Court finds to be reliable. In sum, Bracco presented evidence, at best, showing certain false information was presented to GPO members, but it fails to demonstrate the impact of that information on the members, let alone that it was the substantial reason the contracts were awarded to GEH.

Furthermore, GEH has proffered countervailing reasons, amply supported by testimony and other evidence at trial, why the GPO contracts were awarded to GEH. See Id. ("We have previously rejected inferences of causation based solely on the chronology of events, where the record contains undisputed testimony to the contrary or other equally credible theories of causation.") (string citation omitted). Importantly, with respect to the Novation contract, the Court has found that the Novation TF likely based its evaluation of GEH's bid on personal experience, feedback from physician colleagues, clinical information and the existing strong positive relationship Novation had with GEH at the time. See supra, p 61-62. Even Bracco candidly conceded that it was extremely unlikely that Novation would award a contract to another supplier. Id. There are also various reasons why Contsorta ultimately awarded the bid to GEH. Notably, Consorta conducted its own clinical trials, which contributed to its decision to award the contract to GEH. In addition, Consorta was not only dissatisfied with the low clinical acceptance of Bracco's MRI product, ProHance, Consorta was also dissuaded by its belief that Bracco acted unethically during the bidding process. See supra, pp. 67-73. The Kaiser contract was also awarded to GEH for similar reasons. Indeed, GEH has held a sole source agreement with Kaiser for the supply of x-ray CM since 1993, and with GEH's competitive pricing and favorable relationship with Kaiser, it is not a surprise that GEH received the bid regardless of its Visipaque campaign. See supra, pp. 73-74. Therefore, the Court finds that the GPOs were not materially impacted by GEH's false advertising.

The Court also finds that Bracco has not carried its burden of proving causation for an award of damages under § 35(a)(2) through evidence that GEH's false claims diverted sales from Bracco to GEH or caused GEH to win bids from large accounts (and Bracco to lose bids).[262] As stated above, the relevant inquiry is whether the advertising did in fact contribute materially to the injury. Here, the Court finds that Bracco has not shown that GEH's false advertising was a material factor in both GEH's gains and Bracco's losses. Thus, the Court cannot apply the Account Specific approach to damages, because Bracco has not proved a sufficient causal link between the false messages and the decisions to award the GPO contracts. More importantly, as the Court has found, there were many other factors involved in the bidding process that were credible theories of causation, which influenced the award of GPO contracts to GEH. Likewise, given the substantial number of true messages relating to Visipaque, based on NEPHRIC, VICC and other studies, it is inappropriate to use the Sales Trend Approach since Bracco, through Mr. Malackowski, has failed to adequately distinguish between the impact of the true messages from the false messages.[263]

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[262] "While the plaintiff must prove causation, it does not have to negate every conceivable intervening factor which might have caused a decline in sales." 5 McCarthy § 30:79; see also EFCO, 219 F.3d at 740 n.5. "Proof of a general decline in sales or a disruption of anticipated business growth following the defendant's misconduct can be sufficient in some cases to justify an inference of causation . . . . Proof of a decline in sales combined with evidence tending to discount the importance of other market factors, such as evidence of positive business conditions and the success of similar businesses not subject to the defendant's tortious conduct, can be sufficient to establish a causal connection between the plaintiff's decline in sales and the misconduct of the defendant." See Restatement Third, Unfair Competition § 36, comment h (1995). In this case, Bracco has failed to establish the threshold causation needed for an award of damages as there are other factors present which account for Bracco's lost profits and overshadow GEH's actual false advertising.

[263] While Mr. Malackowski's presentation was illuminating on the issue of damages, Bracco has not proffered sufficient evidence linking its sales decline to GEH's false advertising.

Indeed, given that Bracco and GEH almost exclusively controlled the market in this arena, any losses in Bracco's sales would presumably be GEH's gain. Not surprisingly, Visipaque sales increased after the NEPHRIC study was published. Bracco leaves the Court conjecturing the extent of the sales trend reflecting GEH's false advertising as opposed to the publication of NEHPRIC in the widely respected NEJM, as well as GEH's true messages taken from NEPHRIC and other articles. Without such showing, Bracco is not entitled to lost profits. (Pl.'s FOF ¶¶ 43-73).

As a final note, since the Court declines to award disgorgement of profits it is not necessary to make a damages calculation in connection with its award. Nevertheless, GEH has proven its costs with respect to Visipaque, Omniscan, and Omnipaque sales. If disgorgement were to be awarded, these costs must be subtracted. 15 U.S.C. § 1117(a); (see also Def.'s FOF ¶¶ 173-74).

c. Bracco's Lost Profits Excluding the GPO Contracts

Similarly, Mr. Malackowski's testimony failed to adequately distinguish between the revenue generated by the GOP contracts and sales of Visipaque to individual doctors and hospitals. In fact, Mr. Malackowski testified that with regard to the Account Specific approach, he only analyzed the GEH"s profits derived from the GPO contracts as his sole basis for the damage calculation. See 19 T 56:15-23; 18 T 132:1-21. With respect to the Sales Trend Approach, he took into account all relevant factors and sales, and as such, the Court is unable to differentiate and distinguish the source of the sales by just comparing the numbers derived from the two approaches. In fact, when utilizing the Account Specific approach, Mr. Malackowski yielded a higher number than that of the Sales Trend approach. Indeed, the Sales trend approach "basically calculates sales trends for various products before the publication of the NEPHRIC article, and then determines how the sales of those products diverged from that sales trend after the publication of NEPHIRC." See 19 T 107:3-7. In

addition, because this approach looks at the entire market, it will include all customers. See 18 T 132:13-21. Given the testimony by Mr. Malackowski, the Court has no basis to award damages to the extent that they may have been realized by GEH from the sales of Visipaque to individual doctors and hospitals as a result of false message directed to these customers. Simply put, Bracco has also failed to carry its burden of showing that there is any causal connection between GEH's advertisement effort, including sales calls, using the limited false messages, and the increasing sales of Visipaque to individual doctors and hospitals.

d. Quantifying Bracco's Lost Profit Damages

When quantifying lost profits under the Lanham Act, the Court may "make a just and reasonable estimate of the damage based on relevant data" and "act upon probable and inferential, as well as direct and positive, proof." BASF, 41 F.3d at 1095.[264] The plaintiff's burden of proving the amount of damage is recognized to be lower than proving the existence of damages (i.e., causation) and courts have been inclined to use "limited speculation" in determining an award where it is difficult to ascertain the exact amount of damages as a result of the defendant's violative conduct. GTFM, Inc. v. Solid Clothing, Inc., 215 F. Supp. 2d 273, 305 (S.D.N.Y. 2002); A&H Sportswear v. Victoria's Secret Stores, 967 F. Supp. 1457, 1478 (E.D. Pa. 1997); see also Broan Mfg. v. Associated Distrib., 923 F.2d 1232, 1236, 1240 (6th Cir. 1991). As such, this calculation may be satisfied by circumstantial evidence from which a "probable" or "approximate" loss may be

[264] Contrary to GEH's assertion that Lanham Act damages are "notoriously difficult to prove and unavailable" (36 T 5), courts frequently have upheld multi-million dollar awards. See, e.g., U-Haul Int'l v. Jartran, Inc., 793 F.2d 1034 (9th Cir. 1986) ($40 million); Proctor & Gamble Co. v. Haugen, 2007 WL 1364429 (D. Utah, Mar. 16, 2007) ($19.2 million); Healthpoint Ltd. v. Ethex Corp., 2002 U.S. Dist. LEXIS 26858 *15-16 (W.D. Tex. Dec. 10, 2002) ($16.2 million); First Act Inc. v. Brook Mays Music Co., 429 F. Supp. 2d 429, 438-440 (D. Mass. 2006) ($15.7 million); EFCO, 219 F.3d at 740 ($14.1 million).

ascertained by "reasonable inference." Broan, 923 F.2d at 1236; see also Gilson § 14.03[3][a] ("recovery is not precluded merely because the amount of damages cannot be determined with precision"). Here, the Court finds that Bracco has failed to meet its burden of proof with regard to causation of damages, therefore, no further calculation is necessary.

e. Bracco Has Proven It Had the Capacity to Accommodate the Additional Sales for Which it Claims Lost Profits

GEH also asserts that even if Bracco can establish lost profits, that it may only recover lost profits for sales for which it had the manufacturing and distribution capacity. "To prove capability to meet demand for lost sales, the [plaintiff] need only show a reasonable probability that its manufacturing and marketing efforts were adequate, or could have been made adequate, to make the additional sales. W.R. Grace & Co. v. Intercat, Inc., 60 F. Supp. 2d 316, 322 (D. Del. 1999); Joy Techs., Inc. v. Flakt, Inc., 954 F. Supp. 796, 805 (D. Del. 1996). However, the Court has not found causation with regard any of the GPO contracts. Therefore, it is not necessary for the Court to determine if Bracco had the capacity to fulfill the GPO contract awards it alleges were lost due to false advertising. Nonetheless, the Court finds that Bracco would have had the continuing capacity, given its prior history and business relationship with Consorta, to fulfill a new GPO award with Consorta. The Court reserves judgment as to the Novation and Kaiser awards.[265]

f. Bracco's "Future" (i.e., Post-Injunction) Damages

The standard for proving future lost profits is the same as the standard for proving profits already lost. See Am. Speedy Printing Ctrs. v. AM Mktg., Inc., 69 Fed. Appx. 692, 698 (6th Cir.

[265] The Court notes that it excluded a Bracco letter upon which Bracco's experts relied to support their assumption that Bracco had additional capacity beyond the Consorta contract.

2003); see also Broan, 923 F.2d at 1235 (granting recovery for lost profits on future sales). As discussed above Bracco is not entitled to future lost profit damages.

8. Bracco's Responsive Advertising And Clinical Costs

Under § 35(a)(2), a plaintiff may recover costs incurred for corrective advertising and other damage control expenses incurred in response to a defendant's wrongful conduct. See, e.g., U-Haul, 793 F.2d at 1041; Big O Tire Dealers, Inc. v. Goodyear Tire & Rubber Co., 561 F.2d 1365, 1374 (10th Cir. 1977). No showing of actual customer deception or confusion or of actual marketplace damages is required to collect such damage control expenses, only that (1) there was a likelihood of confusion or damage to sales, profits or goodwill; (2) plaintiff's 'damage control' expenses were responsive to defendant's misconduct; and (3) plaintiff's expenses were reasonable under the circumstances and proportionate to the damage that was likely to occur. Balance Dynamics, 204 F.3d at 690-93.[266]

Having already determined that some of GEH's advertisements were literally false, the first factor is satisfied because the Court applies the presumption of deception and, as such, logically, the consumers were likely confused. Next, GEH argues in a conclusory manner that Bracco's corrective advertising is false and tortious itself, and has not adequately been proven to be linked to alleged false advertising on the part of GEH. GEH has not presented sufficient evidence to substantiate its claim that there is no connection between Bracco's corrective advertising and GEH's false advertising. Indeed, Bracco presented testimony of its damages expert, Mr. Malackowski, to show

[266] Recovery is not limited to advertisements that make specific reference to the defendant or his false claims, nor is plaintiff required to prove that the false advertisements were the sole reason for its expenditures. ALPO Petfoods, Inc. v. Ralston Purina Co., 997 F.2d 949, 952 (D.C. Cir. 1993).

that the expenses spent on corrective advertising were related to the release of the NEPHRIC study and its false promotion by GEH. The Court finds Mr. Malackowski's testimony convincing, particularly since, he spoke extensively with Bracco's officials and reviewed invoices relating to expenses incurred in Bracco's advertising. He opined that Bracco incurred these expenses to counter and blunt the perceived effect of GEH's false advertising, and did so in a manner proportionate to the perceived false advertising. See 19 T 87-95. Accordingly, Bracco has satisfied the second factor. Finally, on cross-examination of Mr. Malackowski, GEH challenged the reasonableness and proportionality of the expenses Bracco spent on corrective advertising by attempting to discredit his calculations. However, Mr. Malackowski's testimony adequately confirms that the amount spent on corrective advertising was reasonable. In addition, the Court notes that the testimony at trial, particularly as to the GPO contracts, revealed hundreds of millions of dollars at stake in the CM market. These staggering numbers support the reasonableness of Bracco's corrective advertising expenditures.

In light of the foregoing, Bracco is entitled to $11,376,500 for corrective advertising performed in response to GE's wrongful conduct ($6,144,000 for 2003 to 2006, $2,182,500 for 2007-June 2008, and $3,050,000 to correct remaining post-injunction misperceptions). (18 T 130-131; 19 T 87-95; P2432, 2434, 2802, 2803, 2699, 4271:tabs33-5). However, the Court finds that Bracco is not entitled to clinical study expenses allegedly incurred to refute GE's false claims because such studies are undertaken as a regular cost of business in the healthcare industry and the Court does not find it equitable to award such costs. (18 T 130-131; 19 T 93, 176-178; P2881, 4271:tab36; D609).

9. Attorneys' Fees

Section 35(a) of the Lanham Act provides: "The court in exceptional cases may award reasonable attorneys' fees to the prevailing party." 15 U.S.C. § 1117(a). A finding that a case is exceptional requires two steps: (1) culpable conduct by the non-prevailing party during the Lanham Act violation or the litigation (e.g. - bad faith, fraud, malice, knowing infringement or willfulness), and (2) a determination by the Court that the circumstances justify altering the general American rule that parties to litigation pay their own attorneys fees (e.g. - closeness of liability, damages suffered by plaintiff). Green v. Fornario, 486 F.3d 100, 103-04 (3d Cir. 2007). The first inquiry by the Court must necessarily be a determination of whether defendants committed some kind of culpable conduct. Ferrero U.S.A. v. Ozak Trading Inc., 952 F.2d 44, 47 (3d Cir. 1991). Courts have awarded attorney's fees based on a finding of willful conduct. Castrol Inc., 169 F. Supp. 2d at 344-345 (In Castrol Inc., the court awarded attorneys' fees based on willful false advertising and rejected defendants' argument that the parties had been engaged in an "honest difference of scientific opinion," stating "Pennzoil's technical staff attempted, although unsuccessfully, to [restrain] Pennzoil's marketing division."); see also BASF, 41 F.3d at 1099 (fees justified where defendant's conduct was deliberate). However, as discussed supra, the Court does not find GEH's conduct to be willful, and furthermore, it does not meet any of the other culpable conduct criteria. Thus, Bracco is not entitled to attorneys' fees and costs.

C. GEH's Counterclaim

a. Bracco's Advertisements were Literally False

GEH alleges that Bracco has disseminated ads in violation of 43(a) of the Lanham Act and New Jersey State Law. As discussed supra pp. 122-26, in order for this Court to find literal falsity

under a "tests prove" standard, GEH must demonstrate that the complained-of advertisements rely on studies, which, even if reliable, do not establish the cited proposition - that studies have demonstrated an increased risk of CIN and nephrotoxicity with Omnipaque as compared to Isovue. GEH contends that Brocco's renal representations for Isovue as compared to Omnipaque explicitly rely on tests, data, and studies. Here, GEH has carried its burden by presenting evidence that tends to show that the Kay study was dramatically different than NEPHRIC and any comparison or extrapolation from the two studies would yield misleading conclusions. Indeed, Bracco's literally false advertisements are akin to GEH's advertisements which this Court has found, see supra, violated the Lanham Act. Accordingly, the Court finds Bracco's advertisements as identified by GEH disseminated literally false messages in violation of § 43(a) of the Lanham Act.

b. Injunctive Relief

During the course of trial GEH stipulated to dropping all claims for damages in its counterclaim, leaving only a request for injunctive relief. (36 T 4-8). In Bracco's Revised Findings of Fact (¶ 96) it stipulated that the Bracco ads and promotions identified by GEH (except D2013) in connection with its counterclaim are no longer in use. Bracco contends that due to this stipulation any injunctive relief against Bracco would have no effect on GEH, Bracco or the market. The Court has already found that the complained-of advertisements were literally false, see supra, in violation of the Lanham Act; however, a showing of literal falsity alone does not entitle the injured party to injunctive relief. Although GEH argues there is a reasonable expectation that Bracco will disseminate the "abandoned" false ads in the future, nonetheless, the Court's findings regarding NEPHRIC and those messages disseminated by GEH that constitute false advertising foreclose the mere possibility that Bracco will reprise their allegedly false advertising. See, e.g., Reader's Digest

Ass'n, Inc. v. Conservative Digest, Inc., 821 F.2d 800, 807 (D.C. Cir. 1987); Robert Stigwood Group, Ltd. v. Hurtwiz, 462 F.2d 910, 913 (2d Cir. 1972) (denying injunctive relief where there is no "cognizable danger of recurrent violation, something more than the mere possibility"); Lurzer v. American Showcase, Inc., 75 F.Supp.2d 98, 101 (S.D.N.Y.1998) (holding that permanent injunction is unnecessary if defendant ceases infringing activity and shows no inclination to repeat offense). In other words, injunctive relief is not appropriate since GEH cannot show it will suffer irreparable harm absent the injunction since the challenged activity has ceased. However, because future disputes may arise following this Court's Opinion, the Court orders that those disputes over Bracco's advertising be submitted to a qualified neutral panel or individual for resolution, in the same manner as ordered by the Court with regard to GEH's advertisements.[267] In the event that Bracco's advertisements are found to be false, Bracco shall bear the costs associated with submitting these disputes. Conversely, if the panel or individual finds that the advertisements are not false, GEH shall be responsible for the costs. Accordingly, the Court denies GEH's request for injunctive relief.

V. Conclusion

For the reasons stated herein, the Court finds that certain of GEH's advertisements constitute actionable commercial promotion or advertisements and are false, but that Bracco has failed to establish causation in connection with its proffered damages. Nonetheless, the Court issues an injunction in accordance with this Opinion, as well as recovery of Bracco's costs associated with corrective advertising. GEH's counterclaim requesting injunctive relief is denied.

[267]For a more detailed discussion, see supra p. 150.

Dated: March 25, 2009

s/ Freda L. Wolfson
The Honorable Freda L. Wolfson
United States District Judge